



3-762

PATENT
660057-2001IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Michael Conor MINOGUE
Michael Louis CROWE

U.S. Appln. No. : 09/902,225

U.S. Filing Date : July 10, 2001

Title of Invention : AN ELECTROTHERAPY DEVICE AND
METHOD

Examiner : Mark Bockelman

Art Unit : 3762

745 Fifth Avenue
New York, NY 10151

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP ISSUE FEE Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 2, 2003.

Edward Nay

(Typed or printed name of person mailing paper or fee)

[Signature]

Signature of person mailing paper or fee

October 2, 2003

Date of Signature

RECEIVED
OCT 10 2003
TECHNOLOGY CENTER R3700COMMUNICATION

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with Applicants' duty to perfect their claim of priority in applications entering U.S. National Stage under 35 U.S.C. § 120 as a continuation of a PCT application,

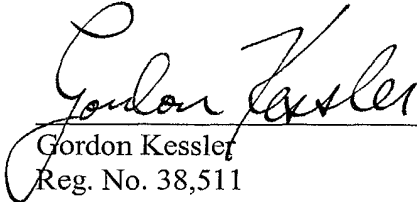
Applicants respectfully submit one certified copy of Irish Patent Application No. S1999/0016 to which priority has been claimed.

REMARKS

Please charge any fees incurred by reason of this communication and not paid herewith to Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By:


Gordon Kessler
Reg. No. 38,511
(212) 588-0800



Patents Office
Government Buildings
Hebron Road
Kilkenny


I HEREBY CERTIFY that annexed hereto is a true copy of the documents filed in connection with the following patent application:

Application No. S1999/0016

Date of Filing 11/01/1999

Applicant BMR RESEARCH & DEVELOPMENT LTD., an
Irish company of Bunbeg, County Donegal, Ireland

Dated this 23 day of September 2003.



An officer authorised by the
Controller of Patents, Designs and Trademarks.

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

BMR RESEARCH & DEVELOPMENT LTD

Address

Bunbeg, County Donegal, Ireland.

Description/Nationality

An Irish company

2. Title of Invention

"Electrotherapy"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date

Country in or for which filed

Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed
by Applicant(s) to be the inventor(s)

MICHAEL CONOR MINOGUE and LOUIS MICHAEL CROWE

Address

Croshua, Kinvara, County Galway, Ireland and 65 Beech Park Road, Dublin 18, Ireland, all Irish citizens.

5. Statement of right to be granted a patent (Section 17 (2) (b))

The applicant has derived the right to be granted a Patent from the inventor(s) by virtue of a Deed of Assignment dated January 8, 1999

6. Items accompanying this Request - tick as appropriate

- (i) ☒ Prescribed filing fee (£ 50.00)
- (ii) ☐ Specification containing a description and claims
- ☒ Specification containing a description only
- ☒ Drawings referred to in description or claims
- (iii) ☐ An abstract
- (iv) ☐ Copy of previous application(s) whose priority is claimed
- (v) ☐ Translation of previous application whose priority is claimed
- (vi) ☐ Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No:

Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name

Address

F.F. GORMAN & CO.

54 Merrion Square,
Dublin 2,
Ireland.

9. Address for Service (if different from that at 8)

F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

F.F. GORMAN & CO., Agents for the Applicants

BY: W. Gorman EXECUTIVE

Signed

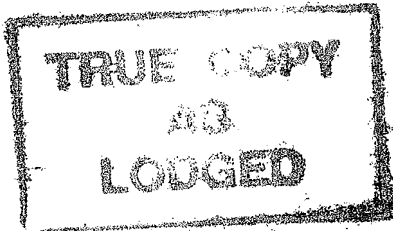
Name(s)

Capacity (if applicant is a body corporate)

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Date January 11. 1999





S 990016
APPLICATION No. _____

"Electrotherapy"

This invention relates to electrotherapy and in particular to a method for stimulating nerves and muscles and to an electrode placement device.

5 In electrotherapeutic methods such as transcutaneous electrical nerve stimulation (TENS) and electrical muscle stimulation, electrodes are applied to the skin and electric currents are passed between the electrodes to stimulate nerve and/or muscle tissues
10 under and between the electrodes. Stimulation can provide pain relief and, where muscles are stimulated, improved muscle tone.

In general, electrotherapeutic methods and devices require the use of an electrical generator unit and a
15 source electrode for transmitting current to a tissue and a return electrode for receiving the current from the tissue. Typically, a microprocessor is employed to issue control signals to a plurality of transducer circuits which drive respective electrode pairs made
20 up of the source electrode and the return electrode.

However, a number of disadvantages are associated with the known methods and devices. For example, frequently electrotherapeutic devices are used by persons with a limited knowledge of anatomy which gives rise to

uncertainty and errors in the placement of electrodes. Accordingly, the electrotherapeutic devices are employed in an inefficient manner. Furthermore, where it is necessary to apply several electrodes to the
5 body, considerable time is expended and wasted in applying the electrodes to and removing the electrodes from the skin.

Moreover, in the methods and devices of the prior art, it is normal to employ pairs of electrodes made up of
10 the source electrode and the return electrode. In addition, use of such electrode pairs is generally restricted to electrode pairs disposed parallel with the direction of muscle fibres.

Accurate placement of electrodes in electrotherapeutic
15 devices and methods is also critical to avoid the creation of a transthoracic route for the current as such routes can theoretically cause cardiac arrhythmias. For example, if electrodes are placed in an incorrect position such as over the lower rib cage,
20 transthoracic routes may be generated thereby theoretically enhancing the risk of cardiac arrhythmia. Accordingly, a need exists for a method and device for the easy and accurate placement of electrodes in electrotherapy.

In addition, electrodes in electrotherapy should be placed in order to avoid passage of current for long distances in deep tissues e.g. it may be deemed undesirable for a current to travel near the ovaries.

- 5 In the electrotherapeutic devices and methods of the prior art, a gel or adhesive gel contact is frequently disposed between the electrode and the skin surface in order to maximise contact between the electrode and the skin surface. However, with use, electrical
- 10 contact with the skin is known to deteriorate and an extra layer of adhesive gel must be added or indeed an entire electrode replaced. The necessity of replacing the electrodes or gel adhesive layer clearly gives rise to additional costs and may require complex
- 15 manipulation by a user thereby resulting in reduced or lack of use of electrotherapeutic devices due to the complexity of replacement.

An object of the invention is to overcome the problems of the prior art.

- 20 A further object of the invention is to provide an improved method for stimulating nerves and/or muscles.

A yet further object of the invention is to provide a method for stimulating nerves and/or muscles in which

transthoracic currents are minimised.

A still further object of the invention is to provide an electrode placement device.

A further object of the invention to provide an
5 electrode placement device having electrode protecting means for protecting electrode contacts.

According to the invention there is provided a method for stimulating a nerve comprising locating an electrode on a locus of a body and applying a current
10 to the electrode characterised in that the locus is identified with reference to an anatomical marker. Preferably, the locus is selected to stimulate a muscle. Suitably, the locus is selected from the group comprising a mid-axillary line, an umbilicus, gluteii
15 and a lower back region.

Advantageously, the muscle is selected from the group comprising abdominal muscles, gluteal muscles and dorsal muscles.

Preferably, the electrode is mounted on a belt.
20 Advantageously, the belt is provided with markers for locating the electrodes adjacent the anatomical markers.

Suitably, at least three electrodes are located on the body. Advantageously, the at least three electrodes comprise at least one common return electrode. More preferably, the at least three electrodes comprise two
5 current source electrodes and one common return electrode.

Advantageously, the current paths defined between electrodes are not necessarily parallel to the direction of the muscle fibres.

10 Suitably, the two source electrodes are disposed on respective mid-axillary lines and the return electrode is disposed adjacent the umbilicus. More preferably, at least a portion of the return electrode is located beneath the umbilicus.

15 The invention also extends to a device adapted to perform the method as hereinbefore defined.

The invention also extends to an electrode placement device comprising a belt adapted to locate electrodes on a body with reference to anatomical markers.

20 Suitably, the anatomical markers are selected from the group comprising the umbilicus, the mid-axillary lines, the glutei and the lower back portion.

Preferably, the electrode placement device further comprises electrodes for applying a current to the body. Advantageously, the electrodes comprise a gel for contacting skin. Suitably, the electrode placing
5 device further comprises reusable release sheets for protecting the electrodes. Preferably, the reusable release sheets are integral with the belt.

The invention also provides an electrode placement device having a switch array for generating a
10 plurality of currents to the electrodes. Various embodiments of the invention will now be described, by way of example only, having regard to the accompanying drawings in which:

Fig. 1 is a schematic front elevation of an
15 abdomen fitted with electrode pairs in accordance with the prior art;

Fig. 2 is a schematic front elevation of an abdomen having right and left electrodes disposed on respective mid-axillary line adjacent the
20 abdomen;

Fig. 3 is a schematic front elevation of the abdomen of Fig. 2 provided with a central umbilical electrode disposed beneath the

umbilicus;

Fig. 4 is a schematic front elevation of an abdomen provided with right and left electrodes disposed along the mid-axillary lines and a central umbilical electrode, the electrodes being formed into a belt mounted on the abdomen;

Fig. 5 is a schematic front elevation of the belt and electrode arrangement of Fig. 4 in which the central umbilical electrode is arranged in a bottom electrode portion disposed beneath the umbilicus and a top electrode portion disposed above the umbilicus;

Fig. 6 is a schematic side elevation of the torso of Fig. 3 with the right electrode disposed along the mid-axillary line beneath the rib cage and above the iliac crest;

Fig. 7 is a schematic side elevation of the torso of Fig. 2 with the left electrode disposed along the mid axillary line above the iliac crest and beneath the rib cage;

Fig. 8 is a schematic rear elevation of human

gluteii with a left electrode disposed on a left buttock, a right electrode disposed on a right buttock and a central lower back electrode disposed on the lower back between the left and right buttock electrodes;

Fig. 9 is a schematic rear elevation of the gluteii of Fig. 8 with the left electrode, the right electrode and the lower back electrode formed into a belt;

Fig. 10 is a schematic front elevation of the abdominal belt of Fig. 4;

Fig. 11 is a schematic front elevation of the abdominal belt of Fig. 5;

Fig. 12 is a schematic front elevation of an abdomen provided with a right electrode, left electrode and central umbilical electrode;

Fig. 13 is a schematic representation of the electrode array of the belt of Fig. 12 provided with a single channel stimulus signal generator;

Fig. 14 is a schematic representation of the currents generated by the electrode array of Fig.

13;

Fig. 15 is a schematic representation of an electrode array similar to the electrode array of Fig. 13 in which the signals from the single channel stimulus signal generator may be balanced;

Fig. 16 is a schematic representation of the current generated by the electrode array of Fig. 15;

Fig. 17 is a schematic representation of an alternative signal generator method employing the electrode array of Fig. 13;

Fig. 18 is a schematic representation of the current generated by the array of Fig. 17;

Fig. 19 is a schematic front elevation of an abdomen provided with the electrodes described in Fig. 5;

Fig. 20 is a schematic representation of a signal generator and the electrode array of Fig. 19;

Fig. 21 is a schematic representation of an

alternative signal generator method employing the electrode array of Fig. 19;

Fig. 22 is a still further arrangement of a signal generator for the electrode array of Fig 19;

Fig. 23 is a schematic representation of the possible current paths generated by the electrode array of Fig. 19;

Fig. 24 is a schematic representation of a signal generator having a pulse sequence generator circuit for the electrode array of Fig. 19;

Fig. 25 is a schematic representation of an array and generator circuit adapted to generate a plurality of current pulses showing the switches employed in the array;

Fig. 26 is a series of schematic front elevations of a portion of a belt in accordance with the invention provided with a releasable sheet for protecting an umbilical electrode made up of a bottom portion and a top portion and Fig. 26b is a series of schematic front elevations of a similar belt having a unitary umbilical

electrode;

Fig. 27 is a schematic front elevation of an alternative abdominal belt in accordance with the invention provided with releasable sheets for protecting the electrode;

Fig. 28 is a further embodiment of an abdominal belt provided with the releasable sheets for protecting the electrodes of the belt;

Fig. 29 is a further embodiment of an abdominal belt in accordance with the invention provided with fold lines and releasable sheets for protecting the electrodes;

Fig. 30 is a schematic front elevation of the belt of Fig. 29 in a folded disposition;

Fig. 31 is a schematic front elevation of an alternative abdominal belt in accordance with the invention;

Fig. 32 is a schematic front elevation of a still further embodiment of an abdominal belt in accordance with the invention provided with releasable electrode protecting sheets;

Fig. 33 is a schematic front elevation of the belt of Fig. 32 in a semi-folded disposition;

Fig. 34 is a front elevation of an alternative abdominal belt in accordance with the inventions;

5 Fig. 35 is a front elevation of a still further embodiment of an abdominal belt in accordance with the invention in an unfolded and folded disposition and;

10 Fig. 36 is a front elevation of a further embodiment of an abdominal belt in accordance with the invention in the folded disposition.

Fig. 1 shows a schematic front elevation of a torso 1 of a person 2 between a chest 19 and a pelvis 4. A rib cage 3 is disposed immediately beneath the chest 19. A
15 left iliac crest 6 and a right iliac crest 7 are disposed between the rib cage 3 from the upper portion of the pelvis 4. An abdominal region or abdomen 5 is defined between the left and right iliac crests 6, 7 and the rib cage 3. An umbilicus 8 is visible on the
20 abdomen 5.

The abdomen 5 is provided with an electrotherapeutic

electrode arrangement in accordance with the prior art made up of a first electrode pair 9, a second electrode pair 10, a third electrode pair 11 and a fourth electrode pair 12. Each electrode pair 9, 10, 5 11, 12 is made up of a source electrode 13 for transmitting current and a return electrode 14 for receiving current from the source electrode. As will be appreciated by those skilled in the art, the first electrode pair, second electrode pair, third electrode pair and fourth electrode pair 9, 10, 11, 12 10 respectively are in general in communication with a microprocessor and signal generator unit which issues respective control signals to a plurality of transducer circuits which drive the respective 15 electrode pairs 9, 10, 11 and 12.

As shown in Fig. 1, in accordance with the electrotherapeutic method of the prior art, up to eight electrodes are employed on the abdomen 5 to achieve an abdominal muscle toning effect. Typically, 20 four of the electrodes, namely the electrode pairs 9, 10 are located over the rectus abdominis muscle and two electrodes, namely the third and fourth electrode pairs 11, 12, over each of the oblique abdominal muscles.

25 Accordingly, stimulation of the abdominal muscles in

accordance with the prior art requires the use of one pair of electrodes per target muscle. Therefore, for complex muscle groups, such of those of the abdomen, a plurality of electrodes is required in accordance with the methods of the prior art resulting in:

- a multiplicity of electrodes and associated wires and connectors
- a requirement on a user to correctly locate the electrodes
- a lengthy set up time and take off time for the electrode pairs 9, 10, 11, 12
- crowding of electrodes on the abdomen
- a multiplicity of controls on the microprocessor for the large number of electrode pairs employed
- confusion over control of individual electrode pairs 9, 10, 11, 12
- confusion over polarity of electrodes (i.e. location of the source electrode and return electrode 13, 14 respectively) and correct placement of the source and return electrodes 13, 14.

Accordingly, in accordance with the method and devices of the prior art, the first second third and fourth electrode pairs 9, 10, 11, 12 respectively are located over a muscle (or closely aligned muscle groups) in

order to stimulate contraction of the muscle. For example as shown in Fig. 1, in the abdomen 5, the rectus abdominis muscle is stimulated by placing electrodes on the overlying skin, above and below the umbilicus 8. Passage of current between the source electrode 13 and return electrode 14 of the first second third and fourth electrode pairs 9, 10, 11, 12 causes excitation of motor nerves innervating the rectus abdominis thereby causing contraction of muscle fibres.

As shown in Fig. 1, the first second third and fourth electrode pairs 9, 10, 11, 12 are typically oriented to be parallel with the direction of the muscle fibres it is desired to stimulate.

Figs. 2 to 7 show various views of the abdomen 5 of Fig. 1 provided with electrodes in accordance with the method of the present invention and also fitted with a device for locating said electrodes in accordance with the present invention.

As shown in the drawings, in accordance with the method of the present invention for stimulating abdominal muscles, a left electrode 15 and a right electrode 16 are mounted on respective left and right mid-axillary lines 17, 18 of the torso 1 of the user

2. The left and right electrodes 15, 16 are located on the respective left and right mid-axillary lines 17, 18 between the rib cage 3 and the respective left and right iliac crests 6, 7.

5 In addition, as shown in the drawings, an umbilical electrode 20 is disposed adjacent the umbilicus 8 between the left and right electrodes 15, 16. The centrally located or umbilical electrode 20 is located substantially beneath the umbilicus 8. The umbilical
10 electrode 20 can serve as a return electrode 14 for the left and right electrodes 15, 16 thereby minimising the number of electrodes required to stimulate the complex abdominal muscle groups.

Surprisingly, the applicants have found that location
15 of the left and right electrodes 15, 16 along the respective left and right mid-axillary lines 17, 18 together with location of the umbilical electrode 20 adjacent the umbilicus 8 results in an optimised electrotherapeutic device and apparatus for abdominal
20 nerve/muscle stimulation. The left and right electrodes 15, 16 may be easily located along the mid-axillary lines 17, 18 which lines serve as anatomical reference markers for optimal location of the left and right electrodes 15, 16. In addition the umbilical
25 electrode 20 may be easily located adjacent and

preferably extending below the umbilicus 8 by reference to the umbilicus 8 which also serves as a constant anatomical reference marker for accurate location of the umbilical electrode 20. Accordingly, the afore-mentioned reference anatomical markers ensure that the electrodes 15, 16, 20 are correctly aligned with target skin and accordingly muscle locations.

Moreover, the applicants have surprisingly found that location of the right and left electrodes 15, 16 along the mid-axillary lines 17, 18 and location of the umbilical electrode 20 adjacent the umbilicus 8 results in efficient and optimised stimulation of the abdominal nerves and muscles without requiring a current path which is broadly co-linear with the direction of the abdominal muscle fibres. Moreover, in accordance with the methods and devices of the present invention, the left and right electrodes 15, 16 and the umbilical electrodes 20 do not require electrode pairs as three electrodes only are required. In addition, stimulation of the rectus abdominis may be efficiently achieved by passing current to and from the umbilical electrode 20 below the umbilicus 8 without the presence of any additional electrode on the rectus abdominis.

Location of the left and right electrodes 15, 16 along the mid-axillary lines 17, 18 ensures effective and optimised stimulation of the transversalis and oblique muscles.

5 The applicants have also found that where the left and right electrodes 15, 16 do not overlap the mid-axillary lines, contraction of the transversalis and oblique muscles dropped precipitously. For example, if the left and right electrodes 15, 16 are placed to the rear of the respective mid-axillary lines 17, 18
10 contraction of back muscles is stimulated instead of abdominal muscles.

In addition, location of the left and right electrodes 15, 16 ensures maximum stimulation of the lower
15 thoracic nerves and subcostal nerve before the said nerves splay out across the abdomen 5.

In short, location of left and right electrodes 15, 16 along the respective mid-axillary lines 17, 18 and location of the umbilical electrode 20 at the
20 umbilicus 8 facilitates stimulation of abdominal muscles where the umbilical electrode 20 is located over the rectus abdominis.

It should be noted that in the arrangement of the

prior art described in Fig. 1 above, a risk exists that inaccurate placement of the electrode pairs 9, 10, 11, 12 can result in the generation of a transthoracic current path. As indicated previously, such transthoracic current paths can theoretically result in cardiac arrhythmias. Accordingly, in the method and device of the present invention, location of the left and right electrodes 15, 16 on the respective left and right mid-axillary lines 17, 18 and location of the umbilical electrode 20 on the rectus abdominis below the umbilicus 8 ensures that current is passed from the left and right electrodes 15, 16 to the centrally located umbilical electrode 20 so that the generation of a transthoracic current route is prevented. Moreover, the aforementioned arrangement minimises the number of electrodes or electrode pairs in order to achieve abdominal muscle stimulation. In the present embodiment of the invention, the number of electrodes required has been reduced from eight as shown in Fig. 1 to three electrodes shown in Fig. 3.

As shown in Fig. 4 elimination of the risk of transthoracic current path generation and effective and reproducible location of the left and right electrodes 15, 16 and the umbilical electrode 20 is achieved in the present invention by the provision of

a belt 21 on which the left and right electrodes 15, 16 and the umbilical electrode 20 are mounted. The belt 21 is placed on the abdomen 5 by reference to the anatomical mid-axillary line 17, 18 markers and the umbilicus 8 marker.

Fig. 5 shows an alternative arrangement of a belt 21 in accordance with the invention in which the umbilical electrode 20 is sub-divided to form an umbilical electrode bottom portion 22 separated from an umbilical electrode top portion 23. The umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 are spaced apart to rest above and below the umbilicus 8 in use.

The belt 21 is adapted to automatically and correctly locate the left and right electrodes 15, 16 and the umbilical electrode 20 correctly on an abdomen to ensure optimum muscle stimulation. Moreover, use of the centrally located umbilical electrode 20, whilst eliminating transthoracic current paths, also serves to ensure that current between the left and right electrodes 15, 16 and the umbilical electrode 20 does not travel for long distances deep in the tissues thereby eliminating current paths via the ovaries in an easily reproducible and efficient manner.

Figs. 8 and 9 show an alternative arrangement of electrodes in accordance with the present invention for causing nerve and muscle stimulation in the glutei 24. As shown in the drawings, the glutei 24 made up of a left buttock 25 and a right buttock 26 are each provided with a left electrode 27 located on the left buttock 25 and a right electrode 28 located on the right buttock 26. A central lower back electrode 29, similar to the umbilical electrode 20 previously described is located between the left electrode 27 and the right electrode 28 at the lower back intermediate the left buttock 25 and right buttock 26. Accordingly, current paths are defined between the left electrode 27 and the central lower back electrode 29 and the right electrode 28 and the central lower back electrode 29 in a manner similar to the electrodes of the abdomen 5 previously described. Therefore, provision of electrode pairs is not required. Moreover, current may be passed between the left buttock 25 and the right buttock 26 to stimulate the glutei muscles.

As shown in Fig. 9, the left electrode 27, the right electrode 28 and the central lower back electrode 29 are incorporated into a buttock belt 30 for automatic correct positioning of the left electrode 27, right electrode 28 and central lower back electrode 29. In

the present embodiment, the lower back region between the left buttock 25 and right buttock 26 serves as an anatomical marker for correct positioning of the central lower back electrode 29 and hence the left
5 electrode 27 and the right electrode 28. Accordingly, the left electrode 27, right electrode 28 and central lower back electrode 29 may be reproducibly and efficiently located by reference to the aforementioned lower back anatomical marker to optimise nerve and
10 muscle stimulation of the gluteii. As shown in Fig. 9, the lower back anatomical marker is indicated by the reference numeral 31. Accordingly, as with the abdominal electrode arrangement described above, electrode pairs are not required and the gluteii can
15 be stimulated employing the aforementioned three electrodes 27, 28, 29.

Fig. 10 shows a front schematic elevation of a belt 1 provided with a left electrode 15, a right electrode 16 and a central umbilical electrode 20 located on the
20 belt 21 between the left electrode 15 and the right electrode 16. As shown in the drawing, the belt 21 is elongate in nature and is provided with a belt fastening buckle 32 device at the ends thereof. The left electrode 15, the umbilical electrode 20 and the
25 right electrode 16 are spaced apart along the length of the belt 21. In a modification to the belt 21 of

Fig. 10, the umbilical electrode 20 can be displaced downwards on the belt 21 with respect to the left electrode 15 and the right electrode 16.

5 The belt 21 is formed from an elasticated portion 33 between the left electrode 15 and the umbilical electrode 20 and the umbilical electrode 20 and the right electrode 16 to facilitate adaptation of the belt 21 to the girth of a user 2.

10 The belt 21 is also provided with a non elasticated portion 34 between the right electrode 16 and the buckle portion 32 and a non elasticated portion 35 between the left electrode 15 and the buckle portion 32. However, if desired, the non-elasticated portions 34, 35 can be elasticated. In addition, the non-
15 elasticated portions 34, 35 can comprise length adjusting means to facilitate adjustment of the length of the belt 21. The belt 21 is contoured or shaped to define a left axillary marker 36 at the left electrode 15 and a right axillary marker 37 at the right
20 electrode 16 so that the belt 21 may be easily aligned with the respective left mid-axillary line 17 and right mid-axillary line 18 anatomical markers. Similarly, the umbilical electrode 20 portion of the belt 21 is contoured as indicated by the reference
25 numeral 71 to identify an umbilical marker 71 for

positioning the belt 21 on a user 2 at the umbilicus 8 anatomical marker. The left axillary marker 36 and the right axillary marker 37 together with the umbilical electrode marker 71 are located on a user at clearly defined anatomical markers namely the left and right mid-axillary lines 17, 18 and the umbilicus 8. Accordingly, a user may readily identify the anatomical markers to correctly locate the belt 21. For instance, the left and right mid-axillary lines 17, 18 may be clearly identified between the respective left and right iliac crests 6, 7 and the rib cage 3.

The belt 21 may be further provided with external markings on the belt 21 to further facilitate correct positioning of the belt 21 on the anatomical markers.

A fixed positional relationship exists between the left mid-axillary line 17 and the right mid-axillary line 18 and the umbilicus 8 in most individuals. The belt 21 can have a further elasticated downwardly disposed portion for supporting the umbilical electrode 20 so that the umbilical electrode 20 can be displaced downwards with respect to the side electrodes 15, 16 to accommodate users 2. Accordingly, the belt 21 is adapted to conform in a correct alignment with the anatomical markers in use. In

particular, the elasticated portions 33 facilitate extension of the belt 21 according to the girth of a user 2. Furthermore the umbilical electrode 20 can move elastically downwards with respect to the belt 21.

Fig. 11 shows a front schematic elevation of a belt 21 similar to the belt 21 of Fig. 10. However, in the present embodiment, the umbilical electrode 20 is formed into a central or umbilical electrode bottom portion 22 and a central or umbilical electrode top portion 23 as previously described in relation to Fig. 5.

As indicated previously, the belt 21 can be formed entirely from an elasticated material with selected areas being non-elastic as required.

The operation of the electrode 15, 16 and 20 of the belt 21 of Fig. 10 will be described having regard to Figs. 12 to 18. As shown in the drawings, the belt 21 is made up of the left electrode 15, the right electrode 16 and the umbilical electrode 13. The left and right electrodes 15, 16 are located on the left mid-axillary line 17 and the right mid-axillary line 18 in use while the umbilical electrode 20 is located in the medial position below the umbilicus 8. The

umbilical electrode 20 acts as a common return electrode 14 for current source to the left electrode 15 or the electrode 16 from a signal generator 38. The signal generator 38 is provided with a signal intensity controller 39. The left and right electrodes 15, 16 are supplied with current from one lead 72a of a lead pair 72 from the signal generator 38. The signal generator 38 is typically a single channel generator 38 where a channel is effectively an independent circuit generating an independent pulse train (as will be appreciated by those skilled in the art, a device in accordance with the present invention may have several channels each generating an independent pulse train which may be phase synchronised with other channels. Generally, the channels of a multi channel stimulator are galvanically isolated from each other to ensure that current cannot pass uncontrolled between the channels and also to provide an isolation safety barrier if one channel becomes electrically live during an electrical fault condition).

Fig. 14 shows a typical pulse pattern generated in the left and right branches of the circuit of Fig. 13. As shown in Fig. 14, the currents generated I_1 , I_2 are approximately the same in each branch of the circuit and travel to the right and left electrodes 15, 16

provided the left and right electrodes 15, 16 are of the same size and impedance - and the tissue impedance is also approximately the same. The umbilical electrode 20 forms the return electrode 14 and a
5 current, I_3 , returned from the umbilical electrode. The current returned is the sum of the currents in the branches shown namely:

$$I_1 + I_2 = I_3$$

Figs. 15 and 16 show an alternative single channel
10 stimulus signal generator 38 similar to the arrangement of Fig. 13 but where the generator is also provided with a balance control 42 for facilitating balancing of the currents I_1 and I_2 . Accordingly, the balance control 40 facilitates the proportion of
15 currents to be varied between 0 and 100%, the sum of the percentages in being 100%. Fig. 16 shows a typical illustration of the proportion of currents.

Figs. 17 and 18 illustrate a further embodiment of a signal generator for use with the left electrode 15,
20 the right electrode 16 and the umbilical electrode 20 of Fig. 12. However, in the present embodiment, the signal generator is made up of a two channel stimulator 38 in which each channel of the stimulator 38 is an independent circuit producing an independent
25 pulse train which may be, but is not necessarily,

phase off-set with respect to the other so that no two pulses coincide. The stimulator 38 is therefore provided with four terminals. Each channel is provided with an intensity control namely a left electrode
5 intensity controller 41 and a right electrode intensity controller 42. Fig. 18 shows a typical timing diagram of the current pulse pattern of each of the three electrodes 15, 16, 20. As shown in Fig. 18, the umbilical electrode 20 is formed from a current
10 pattern which is the composite of the current of the left electrode 15 and the right electrode 16.

As will be appreciated by those skilled in the art, the umbilical electrode 20 of Figs. 12 to 18 forms the return electrode 14 for the left and right electrodes
15 15, 16. However, alternatively, any one or two electrodes 15, 16, 20 could form the source electrode 13 with the remaining electrodes 15, 16, 20 acting as the return electrode 14.

In addition, the electrode array described in relation
20 to Figs. 12 to 18 may also be readily changed dynamically in real time by providing a suitable network of switches which may be semi-conductor, mechanical or electromechanical.

Therefore, it is possible to create at one or more

electrodes 15, 16, 20 of an array, and thereby in the neighbouring tissues, a current pulse train whose principal parameters of amplitude, pulse width and frequency are the sum of the corresponding parameters of other electrodes active at the same time.

Accordingly, the locus of stimulation in an array of electrodes may be varied and a tissue stimulating pattern optimised according to the tissue being targeted by a specific electrode. In contradistinction, in the method and device of Fig. 1, such an effect could only be achieved using electrode pairs in accordance with the prior art with each electrode pair driven with a different pulse train.

Figs. 19 to 25 show various electrode systems and arrays for abdominal stimulation from a left electrode 15, a right electrode 16 and an umbilical electrode 20 formed from an umbilical electrode bottom portion 22 and an umbilical electrode top portion 23.

As shown in Fig. 20, the electrodes 15, 16, 22, 23 are provided with a single channel stimulator 38 similar to the stimulator 38 of Fig. 13. As shown in the drawings, the upper electrodes of the four electrode system namely the left electrode 15, the right electrode 16 and the central electrode top portion 23 operated in unison while the umbilical electrode

bottom portion 22 functions as a common return electrode 14.

Fig. 21 shows an alternative electrode system in which the left electrode 15, the right electrode 16, the umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 are driven from the four terminals of a two channel stimulator 38 similar to the stimulator 38 of Fig. 17. In the present embodiment therefore the left electrode 15 and the right electrode 16 are driven by one channel while the umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 are driven by a second channel. Typically, the first channel and the second channel are galvanically isolated. Each channel is set in use to pulse parameters appropriate to the target muscles e.g. the rectus muscles, the transverse muscles, the oblique muscles and the like. The electrode array of Fig. 21 is effective - in particular where it is desired for the current defined between the left electrode 15 and the right electrode 16 to penetrate deeply into abdomen tissue or the like. However, where such deep penetration is not required the electrode array of Fig. 22 described below is preferred.

As shown in Fig. 22, the electrode array is provided

with two channels as described in relation to Fig. 21. However, in the present embodiment, a first channel is employed to drive the left electrode 15 and the right electrode 16 with respect to the umbilical electrode bottom portion 22 (the return electrode 14).

Meanwhile, the second channel is employed to drive the umbilical electrode top portion 23 with respect to the umbilical electrode bottom portion 22. Accordingly, no transabdominal current path is generated while each of the electrodes of the array is adapted to create current density in the tissue located beneath the electrodes.

As indicated above, the relative current density may be controlled by intensity controllers such as a transverse muscle intensity controller 43 and a rectus muscle intensity controller 44.

In the present invention the umbilical electrode 20 can have a surface area up to the sum of the surface areas of the left and right electrodes 15, 16 so that, depending on the current pulse sequences employed, the current density at the umbilical electrode 20 will be approximate the current density at the left and right electrodes 15, 16. If the area of an electrode, such as the umbilical electrode 20 is too small, over stimulation of a muscle group at that electrode can

result.

Fig. 23 shows a schematic representation of the left electrode 15 (designated L) the right electrode 16 (designated R) the umbilical electrode bottom portion 22 (designated U_1) and the umbilical electrode top portion 23 (designated U_2) as applied to an abdomen 5. Possible current paths between the electrodes are indicated in Fig. 23 using the appropriate letter i.e. the appropriate electrode pair involved and numbered appropriately with Roman numerals. For example, the current path in the abdomen between the electrodes L and R is labelled RL and is numbered VI in the illustration. In accordance with the present invention, the current path identified in Fig. 23 may be used either alone or in isolation for optimum and efficient muscle stimulation to achieve desired results. In order to obviate transabdominal current paths, LR, the L and R electrodes are employed as sources with U_1 and U_2 connected together to form a return electrode. Accordingly, current paths I, II, III and IV provide stimulation over a comparatively broad area of the abdomen. The U_1 and U_2 connections may then be separated and a current path between U_1 and U_2 generated to create a current path $U_1 U_2$ which, in the present example, can boost stimulation of the rectus muscle.

Fig. 24 shows a typical circuit arrangement employing switches to achieve the combination of current paths described in Fig. 23. As shown in Fig. 24 the electrode array is provided with three switches S_1 , S_2 , S_3 controllable by a system microprocessor, (not shown), to control current generation. The switches S_1 , S_2 and S_3 may be relays or semi-conductor circuits. When S_1 and S_2 are closed and S_3 is in the (open) lower position (b) shown in Fig. 24, then current paths I, II, III and IV are enabled. However, with switch S_3 in the upper (b) position the current path V is enabled. Accordingly, through manipulation of the switches S_1 , S_2 and S_3 each pulse in a sequence may be easily directed to a specific current path.

Fig. 25 shows a schematic representation of an array of the invention for controlling current to and between electrodes in electrotherapy e.g. to the left and right electrodes 15, 16 and the umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 hereinbefore described. A first pulse generator 46 and a second pulse generator 47 are in communication with an array of cross point switches, $S_1 - S_{16}$, under the control of a microprocessor (not shown). More particularly, the first pulse generator 46 is in communication with an array of eight switches, $S_1 - S_8$ and the second pulse

generator 47 is in communication with eight switches S_1 - S_{16} . As shown in Fig. 25, the electrodes 15, 16, 22, 23 and the first and second generators 46, 47 define two stimulator channels which may be galvanically isolated from each other. In order to create the current paths III and IV, switches S_2 , S_4 , S_5 of Fig. 25 are closed.

It will be appreciated by those skilled in the art that the switches S_1 - S_{16} may be relays or semiconductor circuits. Alternatively, the switches S_1 - S_{16} may be manually operated.

The microprocessor (not shown) can select on a pulse by pulse basis the current path to be taken by each pulse. Accordingly, the current distribution and effective pulse frequency at each electrode can be optimised for the tissues it is desired to stimulate. Clearly, the array of Fig. 25 can find application in many electrotherapeutic devices - those of the present invention and indeed devices of the prior art such as those described in Fig. 1.

Figs. 26 to 35 show various embodiments of an electrode placement device in the form of a belt provided with protective and reusable release sheets for protecting the electrodes 15, 16, 20, 22 and 23

herein before described. As shown in Fig. 26a, an umbilical electrode 20 formed from an upper umbilical electrode portion 23 and a lower umbilical electrode portion 22 on the belt 21 is provided with an

5 outwardly and laterally extending release sheet 48 disposed above and below the upper umbilical electrode portion 23 and lower umbilical electrode portion 22. The release sheet 48 for each of the said electrode portions 23, 22 is foldable along a fold line 50

10 continuous with the outside edges of the belt 21 so that each release sheet 48 is foldable inwards towards the respective upper umbilical electrode portion 23 and lower umbilical electrode portion 22 to protect the electrode portions 22, 23. The method of folding

15 the release sheets 48 is indicated by arrows in Fig. 26a.

Fig. 26b also show an umbilical electrode 20 provided with two release sheets 48 extending laterally outwards from the belt 21. However, in the present

20 embodiment, the umbilical electrode 20 is not subdivided into an upper umbilical electrode portion 23 and a lower umbilical electrode portion 22. Accordingly, in the present embodiment, the release sheets 48 are foldable inwards along the fold line 50

25 to protect and cover the single umbilical electrode 20.

Alternatively, the double release sheets 48 of Figs. 26a and 26b could be formed from a single release sheet attached to one edge of the belt 21.

Fig. 27 shows an alternative embodiment of a belt 21 in accordance with the invention provided with release sheets 48 on the internal surface of the belt 21. In particular, each of the left and right electrodes 15, 16 and the umbilical electrode 20 disposed on the inner surface of the belt 21 are provided with respective complementary release sheets 53, 52 and 51 also on the internal face of the belt 21 for abutting the respective electrodes 15, 16, 20 upon folding of the belt 21.

Fig. 28 shows an alternative embodiment of a belt 21 in accordance with the invention in which the umbilical electrode extends laterally outwardly downwards when in use from the belt 21 but is nevertheless foldable along a fold line 49 defined at the outside edge of the belt 21. The umbilical electrode 20 is foldable such that the electrode 20 is contacted with the outer surface of the (anatomical) back portion of the belt 21 to protect the electrode surface.

Fig. 29 shows a further embodiment of a belt 21 in

accordance with the invention in which the left electrode 15, the right electrode 16 and the umbilical electrode 20 are spaced apart on the belt 21 by intermediate respective release sheets 56, 58 and 57.

5 The belt 21 is transversely foldable along an axis disposed vertically with respect to the central longitudinal axis of the belt 21 at a fold line 55. Accordingly, folding of the belt 21 along the fold line 55 causes the release sheet 56 to be urged
10 against the left electrode 15, the release sheet 58 to be urged against the right electrode 16 and the release sheet 57 to be urged against the central umbilical electrode 20 to protect the electrodes when the belt 21 is not in use. As shown in the drawings,
15 each release sheet 56, 57, 58 is attached to the belt 21 by a mounting pin 54. The release sheets 56, 57, 58 are reversibly mounted on the belt 21 by the pins 54 so that the release sheets may be replaced as required.

20 Fig. 30 shows an alternative arrangement of the belt 21 showing sheets 56, 57, 58 and the respective electrodes 15, 16 and 20 of Fig. 29.

Fig. 31 shows an alternative belt 21 in accordance with the invention in which the release sheets 56, 57,
25 58 are disposed between the electrodes 15, 16 and 20

as previously described. However, in the present embodiment, the release sheets 56, 57, 58 are hingedly mounted the belt 21 by respective hinge mountings 59, 60 and 61 so that the release sheets 56, 57 and 58 are
5 movable between an electrode protecting position and an electrode exposing position about the respective hinges 59, 60, 61. The belt 21 is foldable along the line 55 as previously described. Provision of hinged non-elasticated release sheets 56, 57, 58 ensures that
10 the elasticity of the belt 21 is not compromised by the release sheets 56, 57, 58. As shown in the drawing, the hinges are located on the release sheets to minimise shearing forces. Accordingly, the hinges are located towards the outer or distant edge of each
15 release sheet 56, 57, 58 with respect to the central umbilical electrode 20.

Figs. 32 and 33 show an alternative belt 21 in accordance with the invention in which the left electrode 15, the right electrode 16 and the umbilical
20 electrode 20 are spaced apart on the belt 21 as previously described. However, in the present embodiment, the respective release sheets 56, 57, 58 disposed between the electrodes are integral with the belt 21 i.e. the material of the belt 21 is adapted to
25 define integral release sheets. Accordingly, as shown in Fig. 33, the belt 21 is foldable such that the

integral release sheets 56, 57, 58 define opposing mating faces in the folded position with the respective electrodes as previously described.

Naturally the release sheets 56, 57, 58 could also be
5 non-integral release sheets as hereinbefore described.

Fig. 34 shows an alternative arrangement of belt 21 in accordance with the present invention in which the left electrode 15 and the right electrode 16 are located on the internal face of the belt 21 as
10 previously described. However, in the present embodiment, the left electrode 15 and the right electrode 16 are separated by three release sheets on the belt 21 namely release sheets 63, 64 and 65. The central umbilical electrode 20 is disposed laterally
15 downwardly and outwardly from the belt 21 opposite to the central release sheet 64. Accordingly, the belt 21 is foldable such that the left electrode 15 is matable against the release sheet 65, the right electrode 16 is matable against the release sheet 63 while the
20 umbilical electrode 20 is foldable upwards against the central release sheet 64.

Fig. 35a shows an alternative arrangement of a belt 21 in accordance with the invention in which the left electrode 15 and right electrode 16 and umbilical

electrode 20 are arranged substantially as described in relation to Fig. 34. As shown in Fig. 35a, in one mode of operation of the belt 21 of Fig. 35a, the umbilical electrode 20 is folded upwards along the fold line 70 towards a central release sheet 75 disposed between a second release sheet 67 and a third release sheet 68 similar to the first release sheet 63 and the third release sheet 65 of Fig. 34. Accordingly, the central release sheet 75 is equivalent to the second release sheet 64 of Fig. 34. In order to affect mating of the electrodes with the releases sheets, the electrode 20 is folded about the fold line 70 against the central release sheet 75 as described above. The belt 21 is then folded about a fold line indicated by the reference numeral 69 disposed transversely to the fold line 70 so that the right electrode 16 is mated against the release sheet 68 and the left electrode 15 is mated against the release sheet 66.

Alternatively, where the umbilical electrode 20 is of increased area and impinges upon the area occupied by the central release sheet 75 in Fig. 35a, the release sheet 67 may be a hinged release sheet similar to the hinged release sheets previously described. However, in the present embodiment, the release sheet 67 is disposed parallel to the fold line 69 at the proximate

end of the release sheet 67 adjacent the central
release sheet 75 in Fig 35a. Accordingly, in order to
effect mating of release sheets with the electrodes in
the present embodiment, the release sheet 67 is first
5 hinged about the hinge 76 to occlude the area of the
"release sheet" 75. The dependent umbilical electrode
20 is then folded about the hinge 70 onto the turned
over release sheet 67. The belt 21 is then folded as
indicated above for the belt 21 of Fig. 34.

10 Fig. 36 shows an alternative embodiment of a belt 21
in accordance with the invention. The belt 21 of Fig.
36 is broadly similar to the belt of Fig. 35a i.e. the
umbilical electrode 20 extends into the area occupied
by the central release sheets 75 of Fig. 35a. In order
15 to effect closing of the belt 21 of Fig. 36, the belt
21 is first folded at the fold line 69 indicated in
Fig. 35a. The dependent umbilical electrode 20 is then
folded along the fold line 70 to mate against the back
or reverse of the belt 21 i.e. on the reverse side of
20 the belt 21 contiguous with the area occupied by the
release sheet 67 in Fig. 35a. Accordingly, the
dependent central umbilical electrode 20 is protected
by the reverse face of the belt 21.

The invention also provides an array for a controller
25 for electrotherapy in accordance with the invention in

which a plurality of current pulses may be applied to the electrodes and in turn muscles for stimulation in various permutations and combinations according to the arrangement of switches employed in the array.

5 Therefore, the array facilitates the use of various pulse types to effect stimulation of muscles.

As indicated above, the release sheets herein described may be located on the inner or outer surface of the belt 21 and may be integral with or attached to
10 the belt 21. In addition, the release sheets may extend laterally outwardly from the belt 21 and may be foldable with respect to the belt 21.

The release sheets herein before described do not interfere with stretching of the belt 21 of the
15 invention in order to accommodate a user 2. In one embodiment of the invention, the release sheet of the belt 21 may be of elastic or plastics material while, where desired, the release sheets may be adapted to be inelastic at desired locations on the belt 21 to
20 control elasticity of the belt 21.

In an alternative embodiment of the invention, the electrodes of the belt 21 may be oriented and spaced apart along the belt 21 to share a common release sheet attached to the belt 21.

Moreover, as indicated above, the belt 21 may be adapted to define or comprise integral release sheets for protection of the electrodes.

In an alternative embodiment of the invention, the umbilical electrode 20 can be found on a stiffened portion of the belt 21 to prevent curling of the umbilical electrode 20. Moreover, the umbilical electrode 20 can be located on the reverse or rear of a portable control unit integral with or mountable on the belt 21. The electrodes 15, 16, 20 and in particular the central lower back electrode 29 can be found from a resiliently deformable material to adapt to the shape of an individuals anatomy e.g. the concave shape of the lower back.

In another embodiment of the invention, the electrode surfaces may be framed with an area that will attach to an adhesive gel of the electrode relatively strongly e.g. in this case the gel-pad area is larger than the electrode area. In another embodiment of the invention, the planar surfaces of the gel electrode layer may have different tactile properties. For example, a designated, relatively adhesive side may be attached to the electrode surface. In a still further embodiment of the invention, the replacement gel-pad skin contact surface may be framed at its perimeter

with a single sided adhesive tape. The adhesive side may be in contact with the outer margin of the gel while the tape extends around the margin of the gel. For example, the tape may also share a common release sheet with the electrode contact side of the gel-pad while upon removal of the (inner) release sheet, the combined pad-tape unit may be firmly applied to the inner belt/electrode surface. Use of the adhesive tape minimises risk of the gel-pad fraying at the edges, moving in use or becoming dislodged from its designated site. However, it is not necessary for the tape element to extend about the entire periphery of the gel-pad. For example, the tape element may simply include or protect selected edges or corners.

In a still further embodiment of the invention, the belt 21 may be provided with a recess or a raised area ensuring proper positioning and locating of electrodes. The raised area may be a plateau for direct electrode pad placement or a raised ridge framing the surface for electrode pad placement. The recess may be adapted to comprise suitable dimensions. The recess may also be adapted to define a cleft-like depression. The cleft may be dimensioned to accommodate the electrode gel-pad edges or selected edges only. The provision of such a recess ensures that shearing forces on the electrode pad surface are

unlikely to lift the electrode gel pad from its designated locus.

In a still further embodiment of the invention, the periphery (or selected outer margin) of the skin
5 contacting electrode gel pad may have reduced adhesive properties. The periphery or selected outer margins may have the reduced adhesive properties by coating or covering the periphery or the selected outer margins with suitable material. Accordingly, shearing forces
10 on the electrode surface are unlikely to lift the electrode pad from its designated locus.

In a still further embodiment of the invention, the edges or selected edges of the electrode pad may be sloped. In this embodiment of the invention, the non
15 sloped portion of an electrode may be designated as an electrode contacting surface so that shearing forces on the electrode surface are less likely to lift the electrode from its designated locus.

It is also envisaged in an alternative embodiment of
20 the invention that the edges, or selected edges of the gel-pad may be held in position by flaps, clips, tabs and the like.

As indicated previously, a user 2 positions a first

marker on the belt 21 at an anatomical marker e.g. the mid-axillary lines 17, 18 or the umbilicus 8 as appropriate and subsequently stretches the belt to the next anatomical marker and, if available, further anatomical markers for closing the belt 21. The belt 21 can be tightened, if necessary at the buckle 32 in a manner similar to airline safety belts or by utilising overlapping velcro surfaces as the fastening method.

10 The belt 21 is applied in a wrapping motion which has the effect of bringing each electrode into contact with the skin in a direction which is normal to the skin surface thereby avoiding shearing movement which tends to wrinkle electrode surfaces - especially when
15 the electrodes are adhesive faced.

For example, where the electrode placement device in accordance with the invention is an abdominal belt 21 as previously described, the preferred method of mounting the belt 21 on a user 2 is to align the
20 abdominal marker while the belt is held fully extended. Each end of the belt is then brought back posteriorly, stretching as necessary to align the mid-axillary line marker and the belt 21 is finally closed and possibly tightened at the posterior.

In one embodiment of the invention, the belt 21 is provided with electrodes in the form of rubber pads mounted on the inner surface of the belt 21. The belt 21 may be connected to a generator unit 38 as

5 previously described by wires integrated within the belt by means of an inserted pin or clothing fastener. Conductive electrodes may be attached to the belt 21 by gluing, vulcanising, sewing, clamping or the like. Within the belt, current may be distributed through

10 longitudinal stripes formed by conductive fibres separated by stripes of insulating material which are used to pass current between the generator 38 and the electrodes. Suitably, conductive flexible material may be employed at designated points on the inner surface

15 of the belt 21 to connect the conductor stripes to the skin, the patches of conductive material being so placed at the one designated conductive stripe. The conductive flexible material may be fabric, metal foil, carbon loaded film, hydrogel, fluid filled

20 sponges or the like. The conductive stripes may be covered by insulation except in specific localised areas where the conductive stripes are exposed without contact with the skin directly or indirectly by means of a patch of flexible conductive material or

25 conducted fluid.

Accordingly, in use, a user 2 simply holds the

extended belt 21 in a substantially horizontal disposition with one end at each of the belt 21 adjacent the buckle 32. The user 2 then urges the belt 32 towards the abdomen 5 such that the umbilical electrode 20 of the belt 21 approximates to the umbilicus 8. The user 2 then moves the buckle 32 at the ends of the belt 21 posteriorly to locate the left and right electrodes 15, 16 along the respective mid-axillary lines 17, 18 before finally closing and fastening the belt 21 with the buckle 32. The elasticated portions 33 of the belt 21 ensure that size difference between subjects can be accommodated.

It should be appreciated that the buckle 32 of the belt 21 of the invention may be formed from a plastics buckle, velcro or the like.

The method of use of the belt 21 ensures the approximation of the adhesive surface gel electrodes to the skin in a direction substantially normal to the skin surface thereby avoiding shearing movements.

The advantages of the invention are many. The invention facilitates the accurate placement of electrodes on the skin to ensure that stimulation currents for electrotherapy purposes are confined to the target area and are delivered at the most

effective loci. Furthermore, the belt device of the invention facilitates the application of moderate pressure over the surface of an electrode in contact with the skin thereby reducing electrical impedance of the skin-electrode contact to maximise efficiency. Although the applicants do not wish to be bound by any theorem, it is believed that impedance is reduced due to enhanced contact of the semi-fluid electrolyte of the conductive medium of the electrode with the microscopic uneven surface of the skin.

The present invention therefore provides a belt device which incorporates a plurality of electrodes fixed to the belt and which can be fitted around the girth, limbs etc of the body to locate on easily identifiable anatomical markers. The device of the invention may be adapted for use on various anatomical parts such as the abdomen, buttocks, limbs and like. The position of the electrodes within the belt ensures that when the belt is correctly aligned with obvious anatomical markers that the electrodes are then automatically aligned correctly with the target's given location. The device and method of the invention is also adapted to minimise the risk of transabdominal and transthoracic current flows by passing current by lateral electrodes to more centrally located electrodes. For example, where the device and method

of the invention is employed for abdominal muscle stimulation, central electrodes are placed on the skin overlying the rectus abdominis muscle (adjacent the umbilicus) and stimulation of the rectus abdominis is achieved in addition to the oblique muscles and the transversalis muscles. In addition, such an electrode arrangement allows for a reduction in the total number of electrodes e.g. from as many as eight to three or four electrodes.

10 In addition, incorporation of the electrode positions in accordance with the invention into a "wired" belt - like structure ensures proper orientation of the electrodes and precludes the possibility of inadvertent sending of current in a potentially hazardous direction such as deep into tissues. Moreover, elastication of the belt of the present invention facilitates use of the belt type arrangement with users of varying sizes.

The method and apparatus of the invention has particular application in the application of electrical current to abdominal and gluteii muscles. In addition, the method and device of the invention may be employed in the stimulation of lower back musculature.

The method and device of the invention is suitable for use with various types of electrodes such as gel adhesive or carbon - rubber electrodes.

5 The provision of a belt - type device incorporating electrodes in accordance with the present invention eliminates loose wiring, incorporates electrode protection and allows for rapid and accurate electrode placement.

10 The invention also provides an array for a controller for electrotherapy in accordance with the invention in which a plurality of current pulses may be applied to the electrodes and in turn muscles for stimulation in various permutations and combinations according to the arrangement of switches employed in the array.

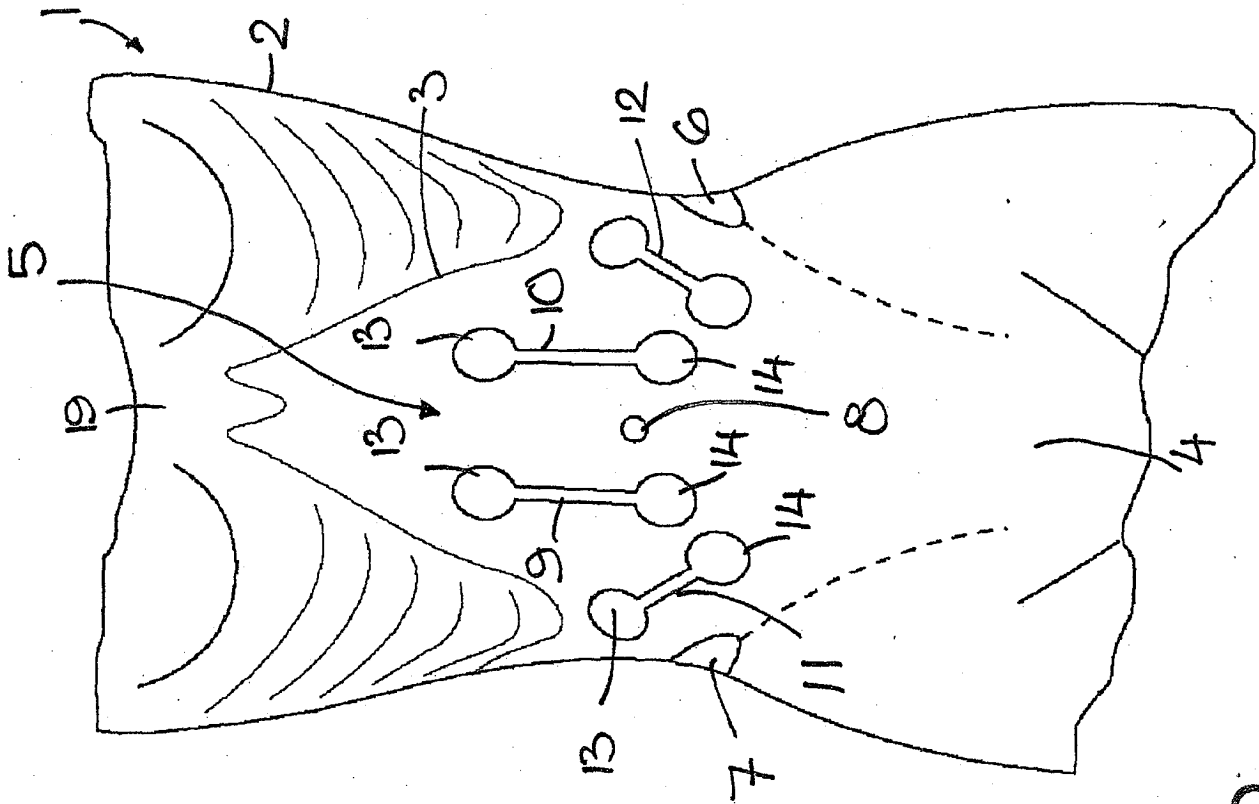
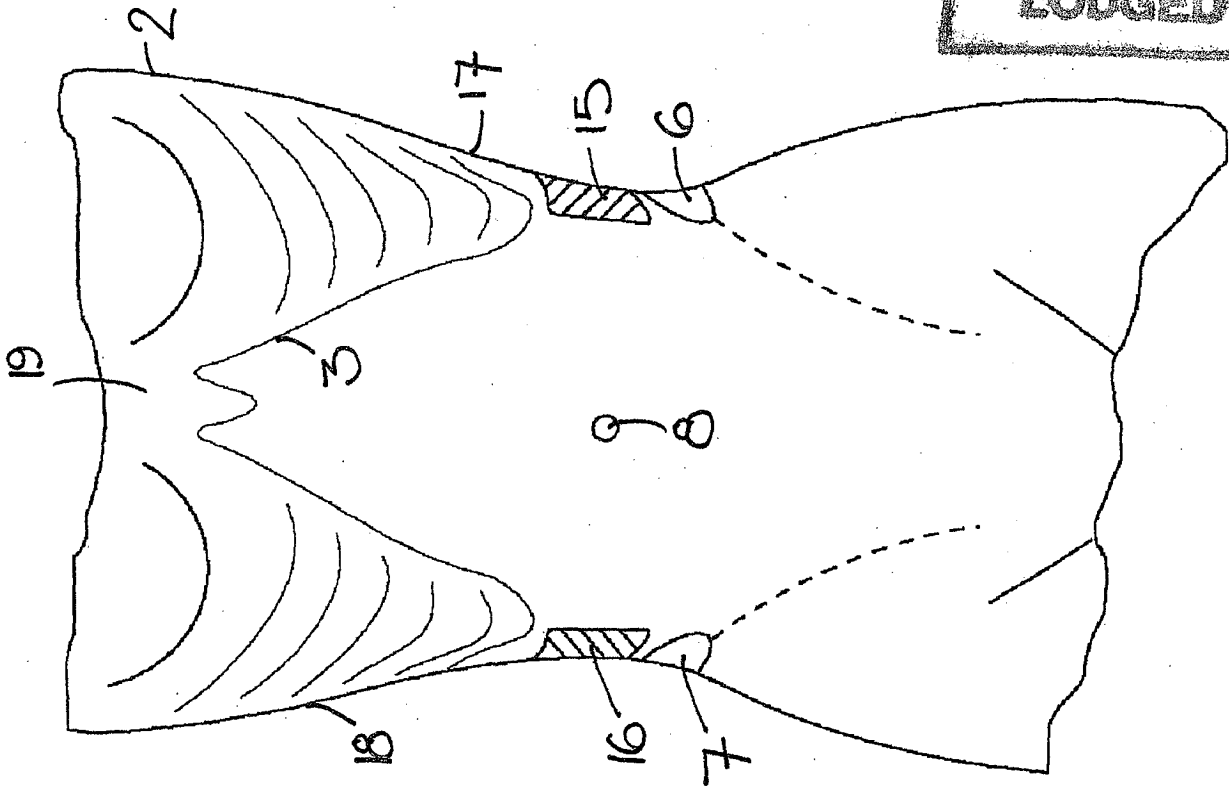
15 Therefore, the array facilitates the use of various pulse types to effect stimulation of muscles.

20 In addition, the present invention eliminates the requirement of a separate wiring system, cover and backing in gel - type electrodes. Finally, the use of removable release sheets in combination with gel - type electrodes ensures protection of the electrode and prolongs the longevity of the electrode.

The invention is not limited to the embodiments herein described which may be varied in construction and detail.

F.F. GORMAN & CO.

TRUE COPY
AS
LODGED



INFORMAL

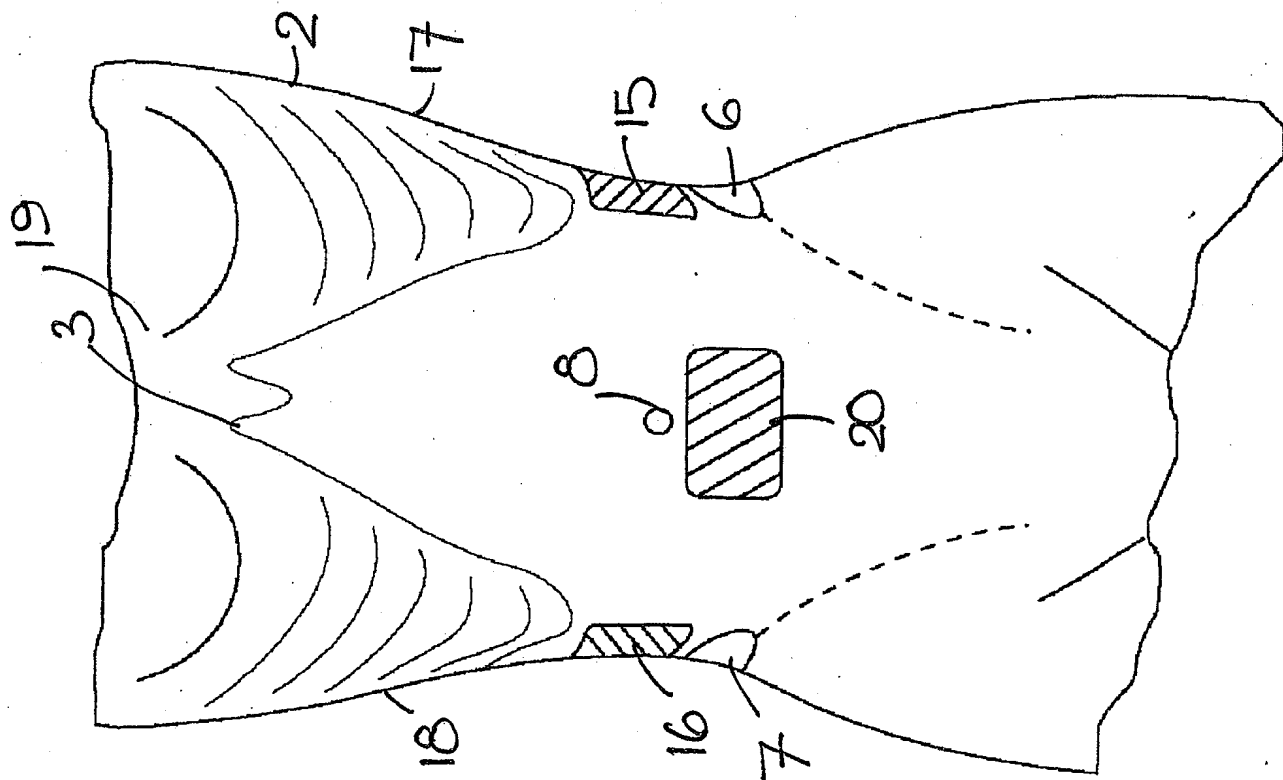


FIG. 3

INFORMA

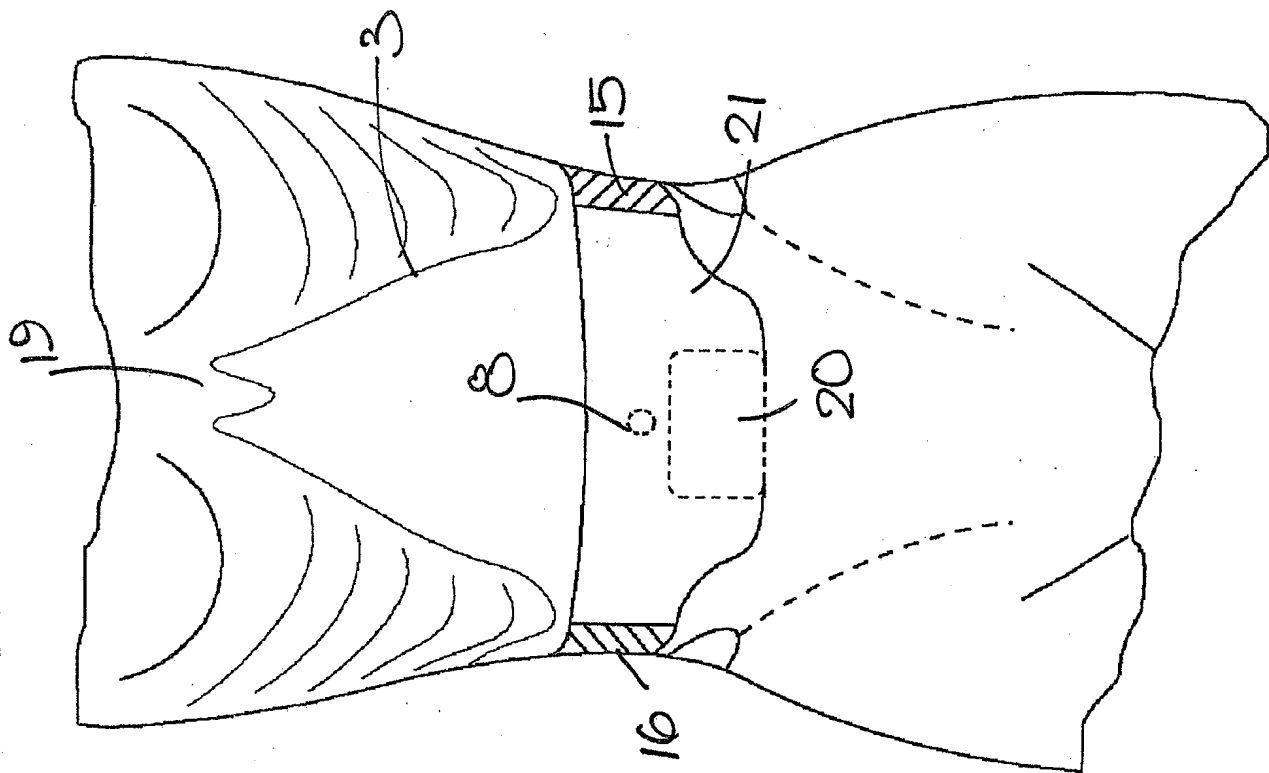


FIG. 4

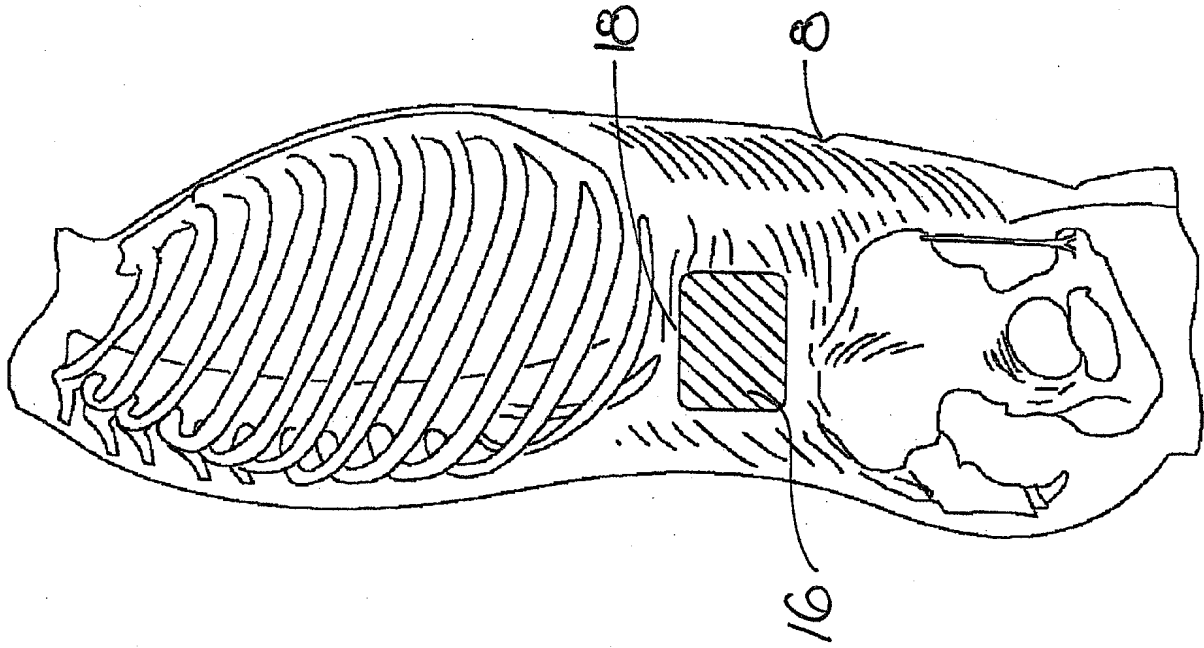


Fig. 6

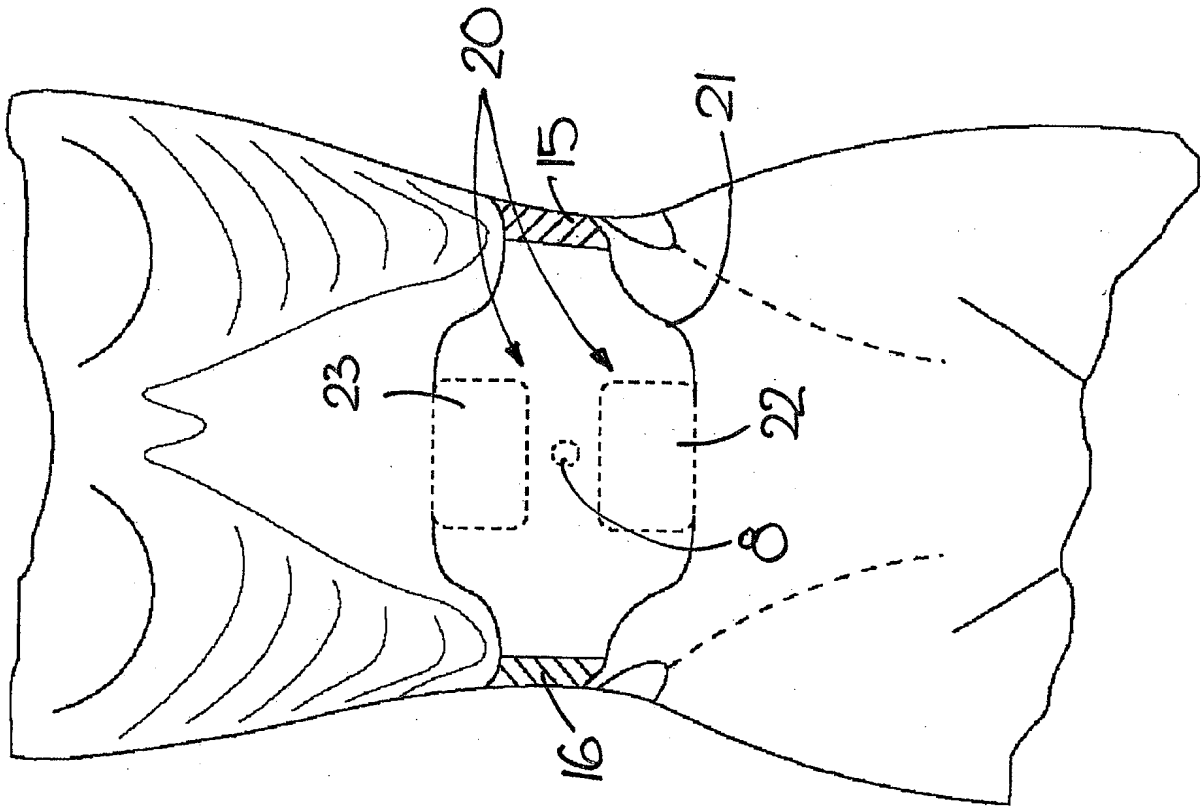


Fig. 5

INFORMA

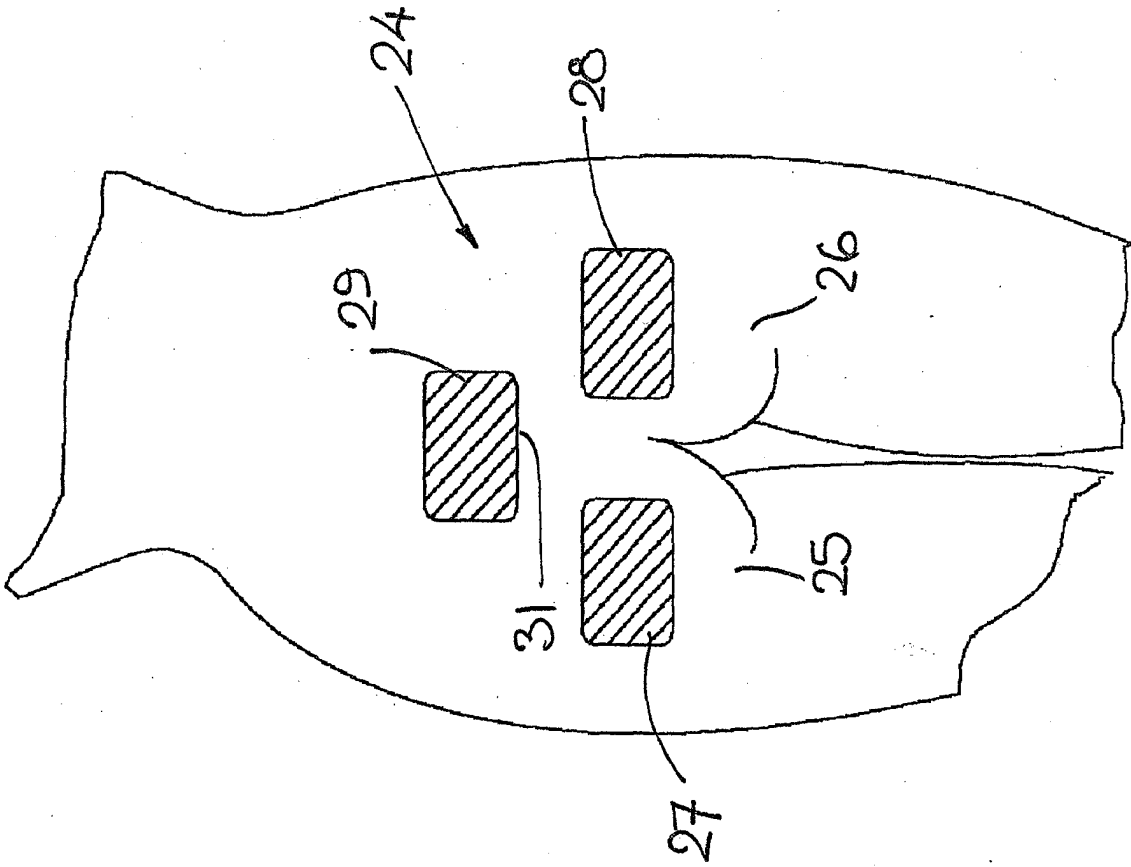


Fig. 8

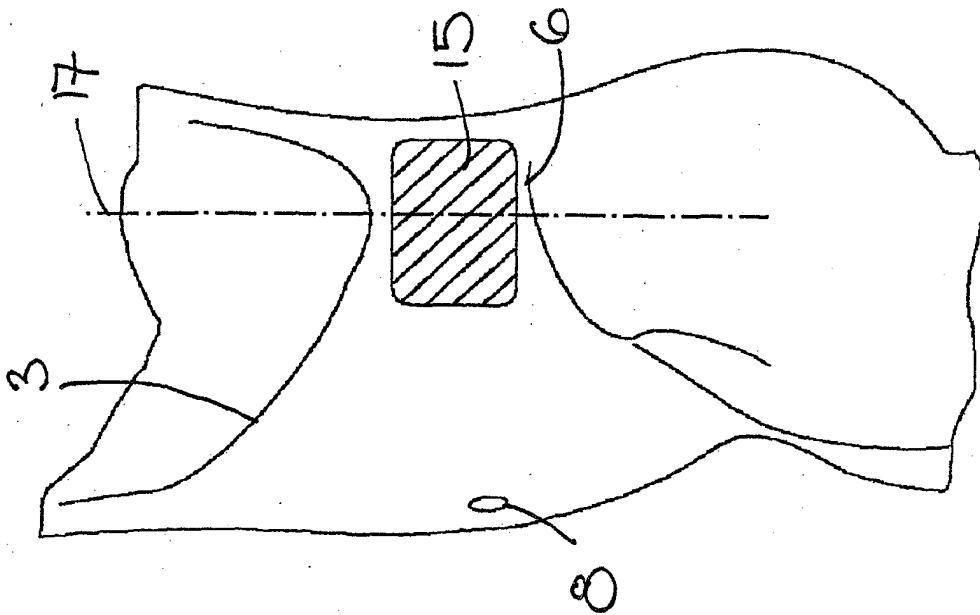


Fig. 7

INFORMAL

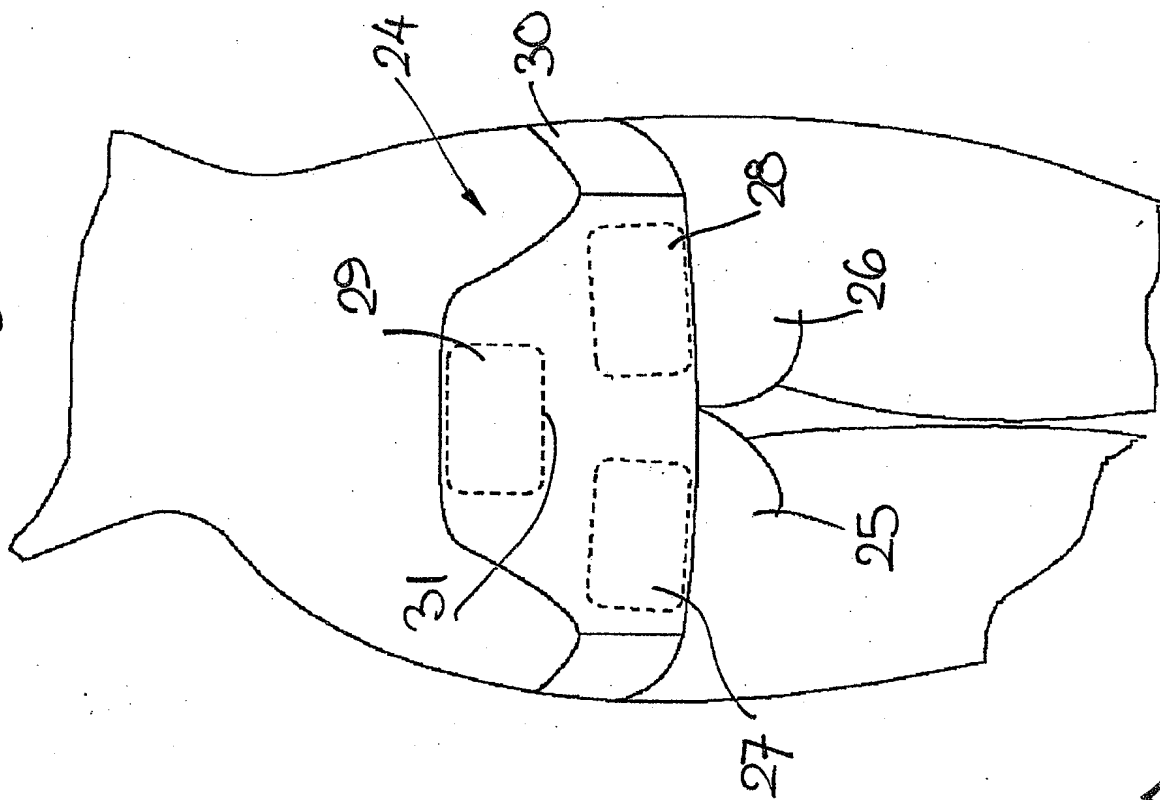


Fig. 9

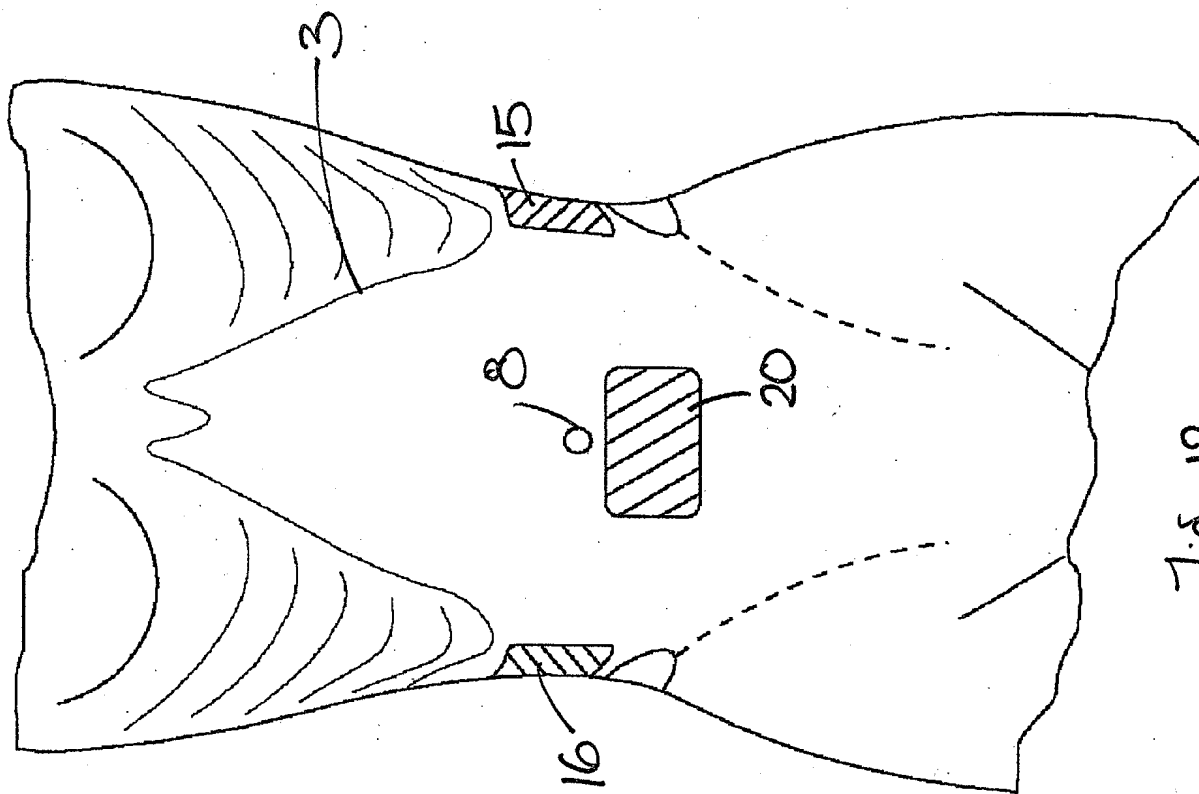
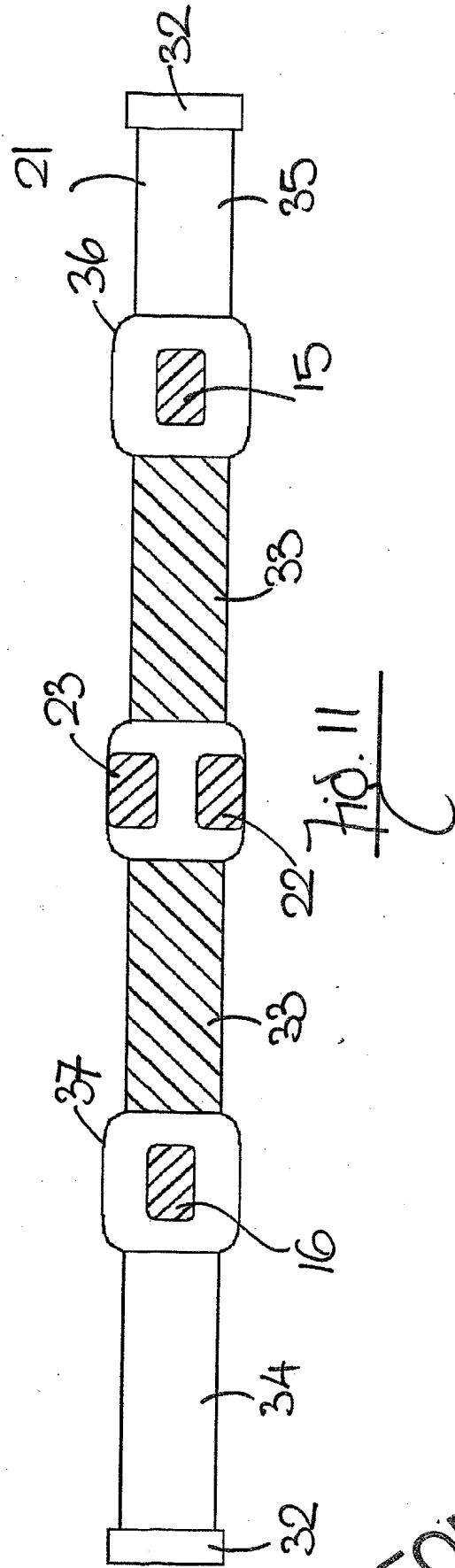
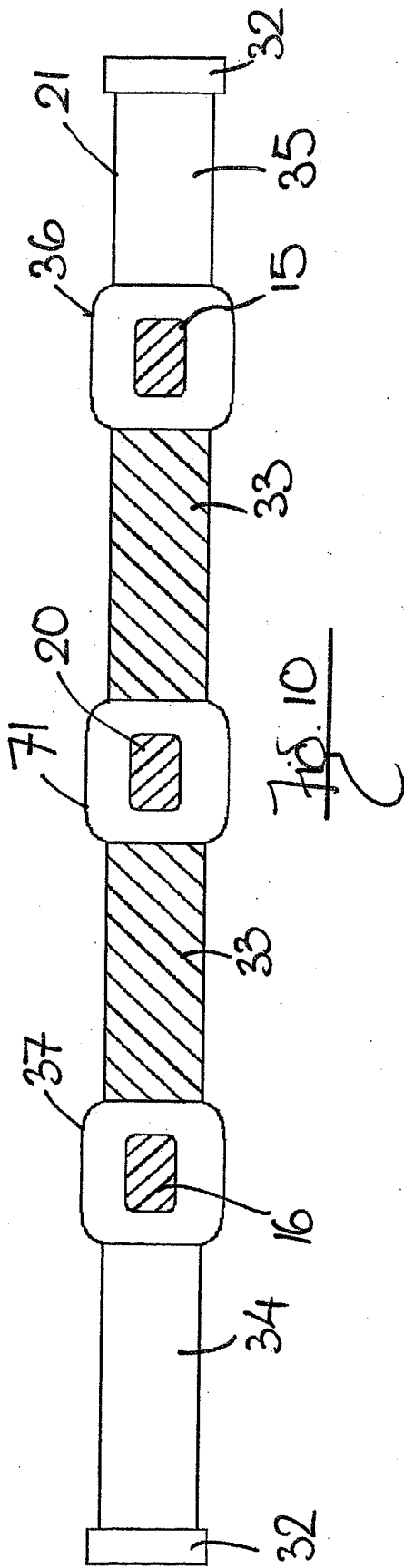


Fig. 12

INFORMAL



INFORMAL

7/16

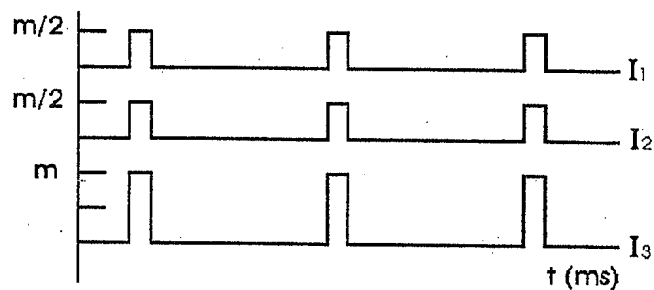
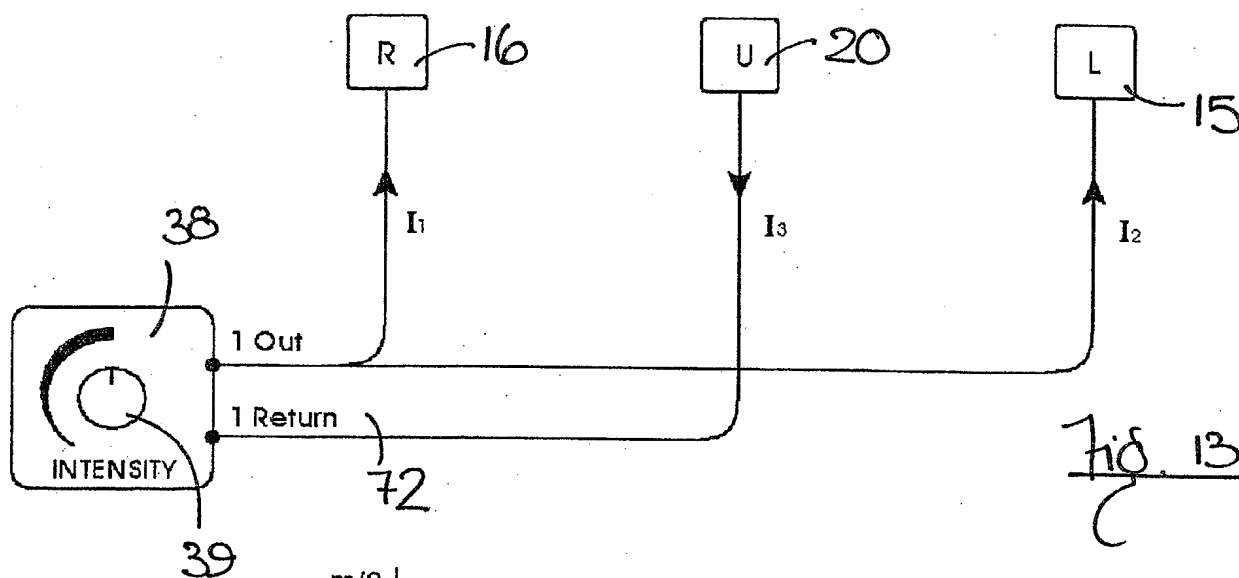
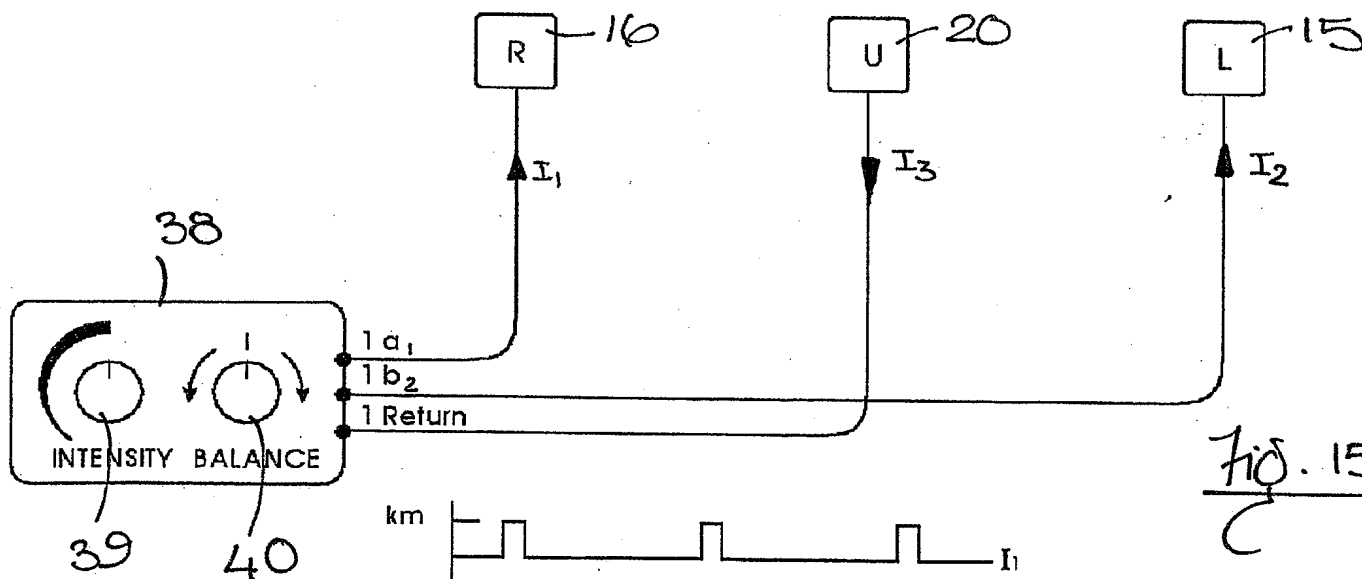


Fig. 14



$$(1-K)m$$

$$0 \leq K \leq 1$$

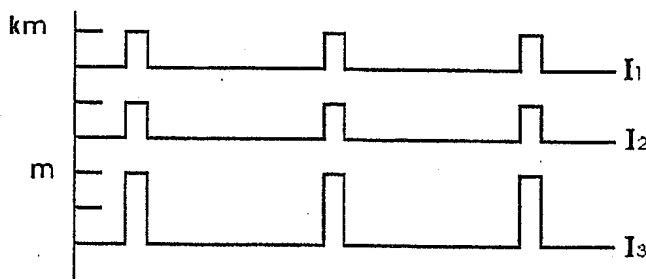


Fig. 16

INFORMAL

8/16

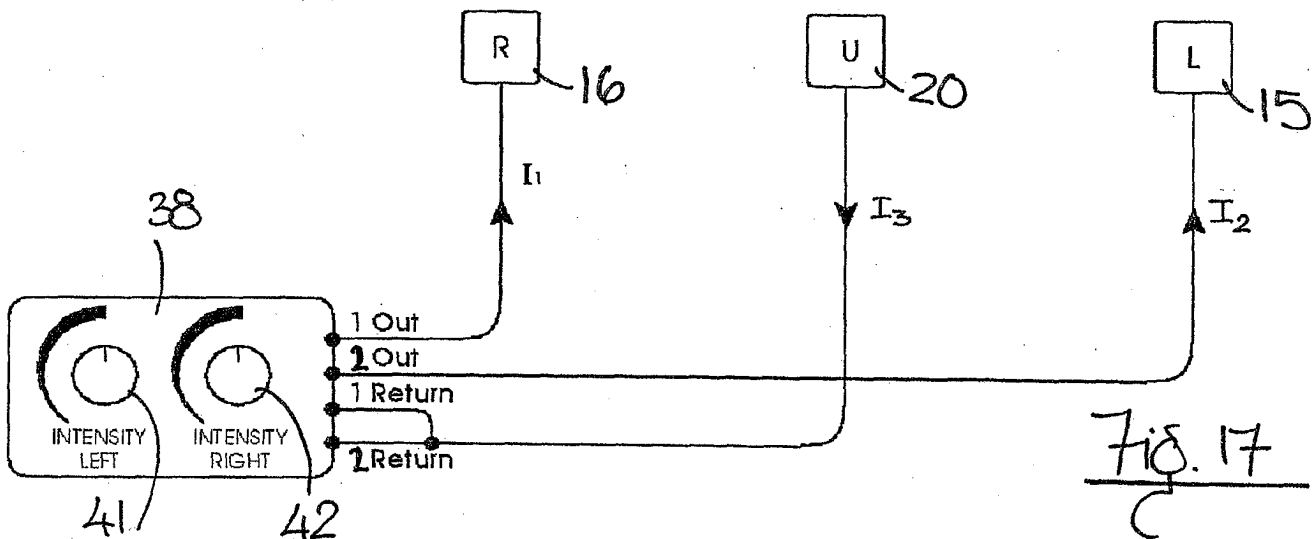


Fig. 17

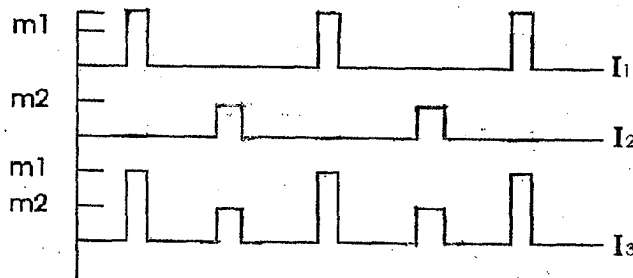


Fig. 18

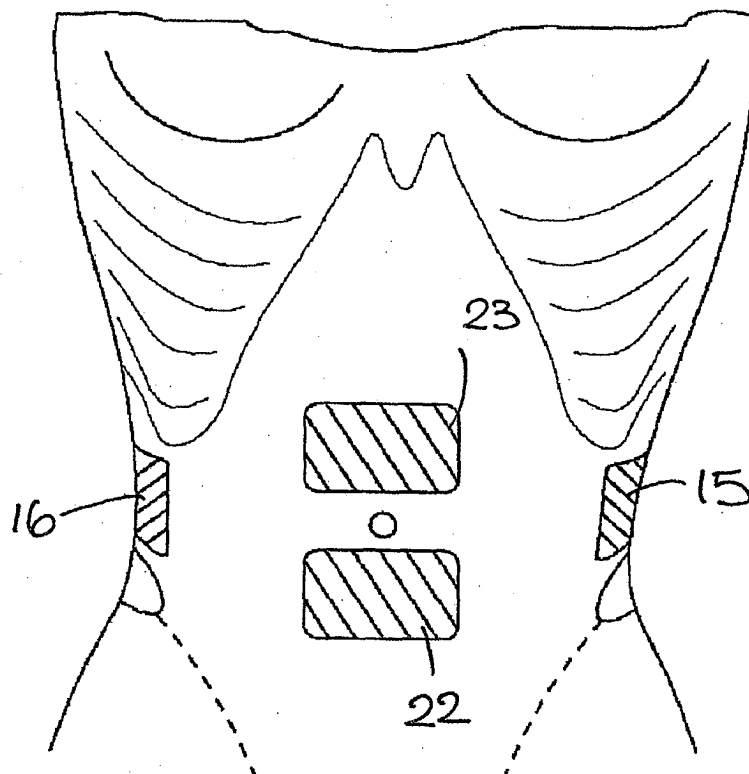


Fig. 19

INFORMAL

9/16

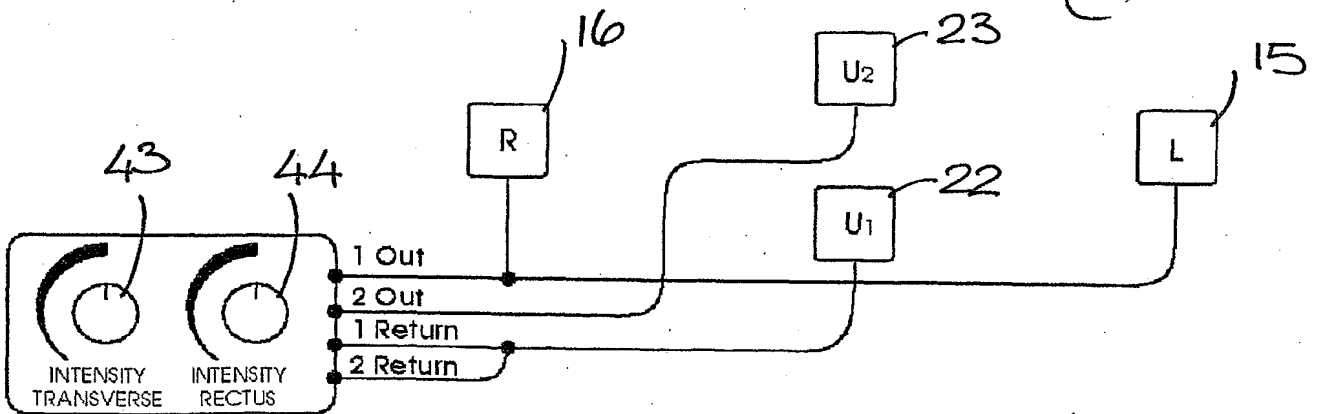
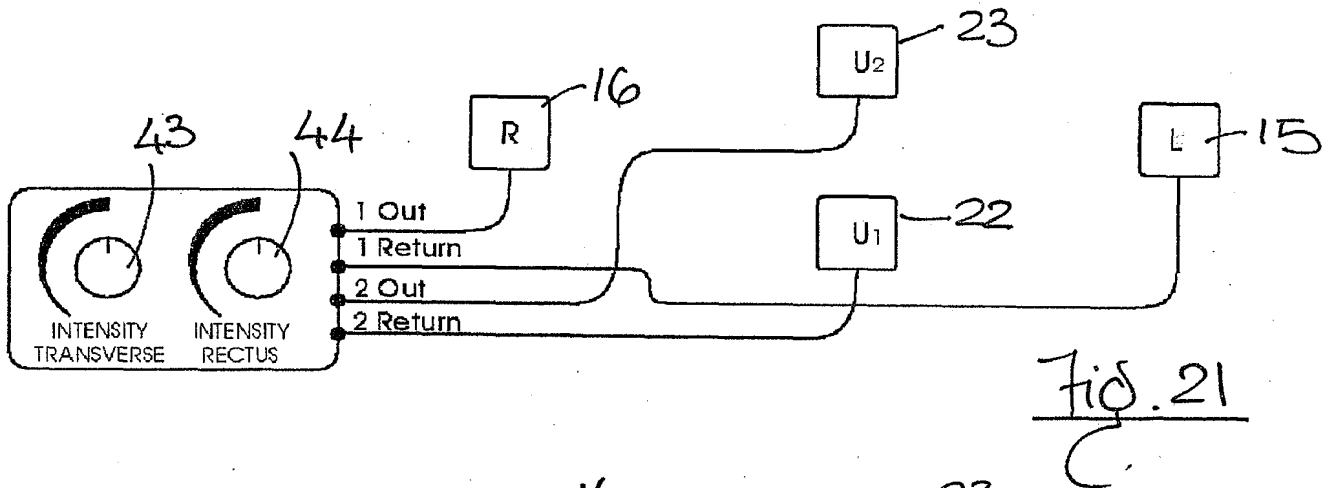
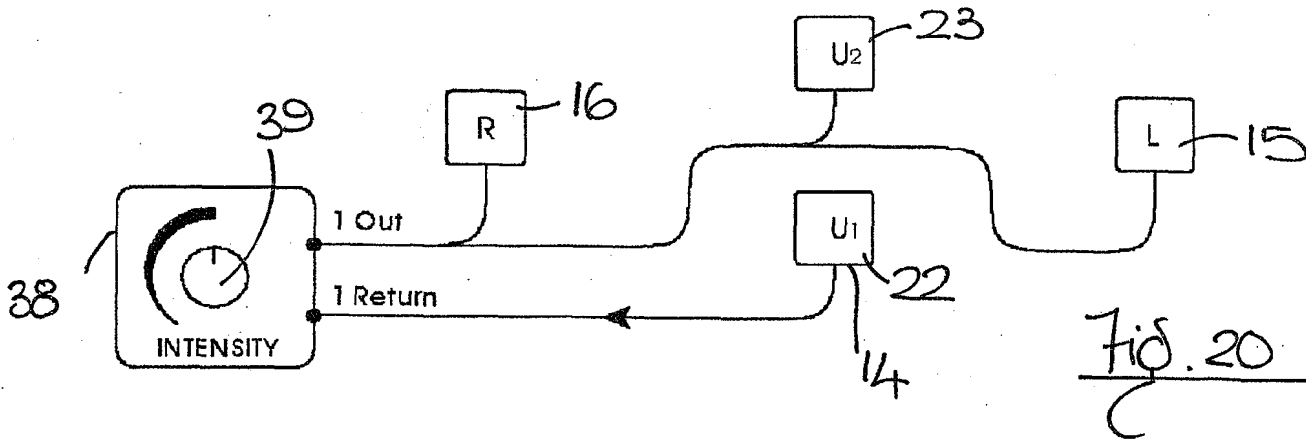
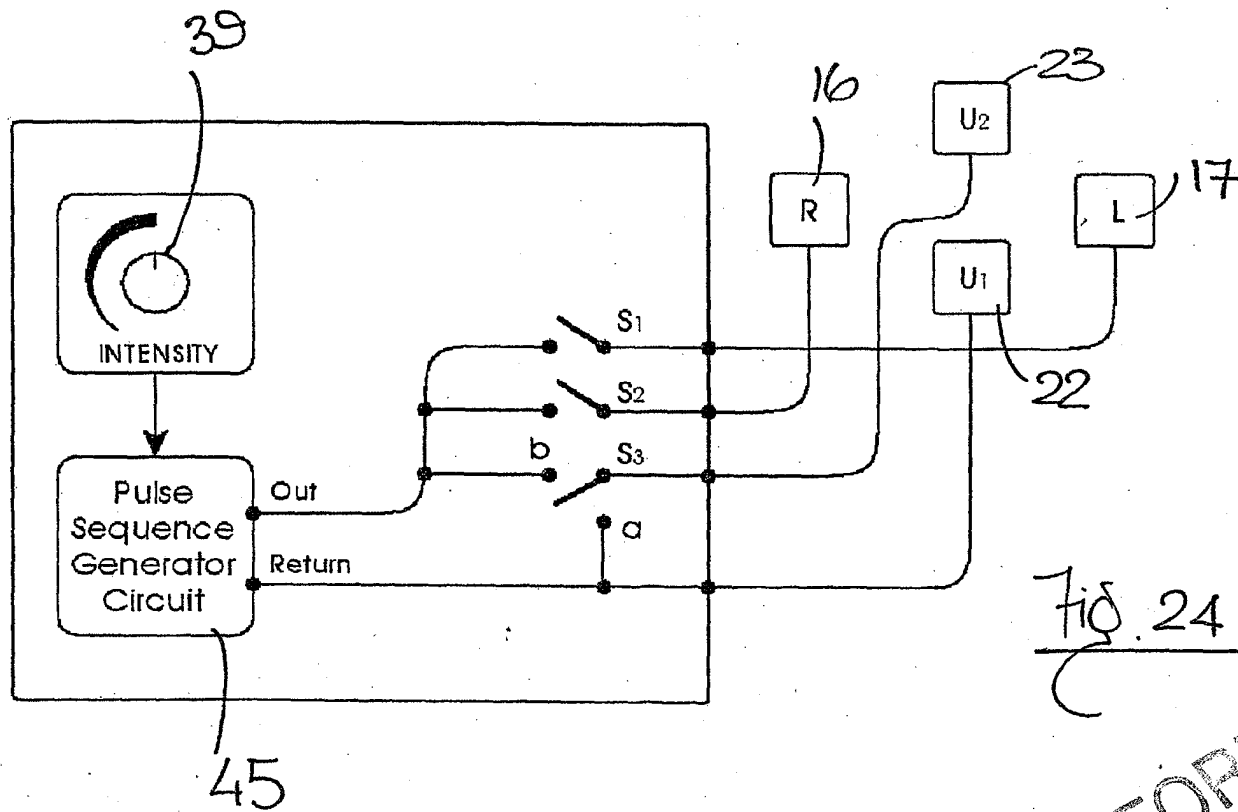
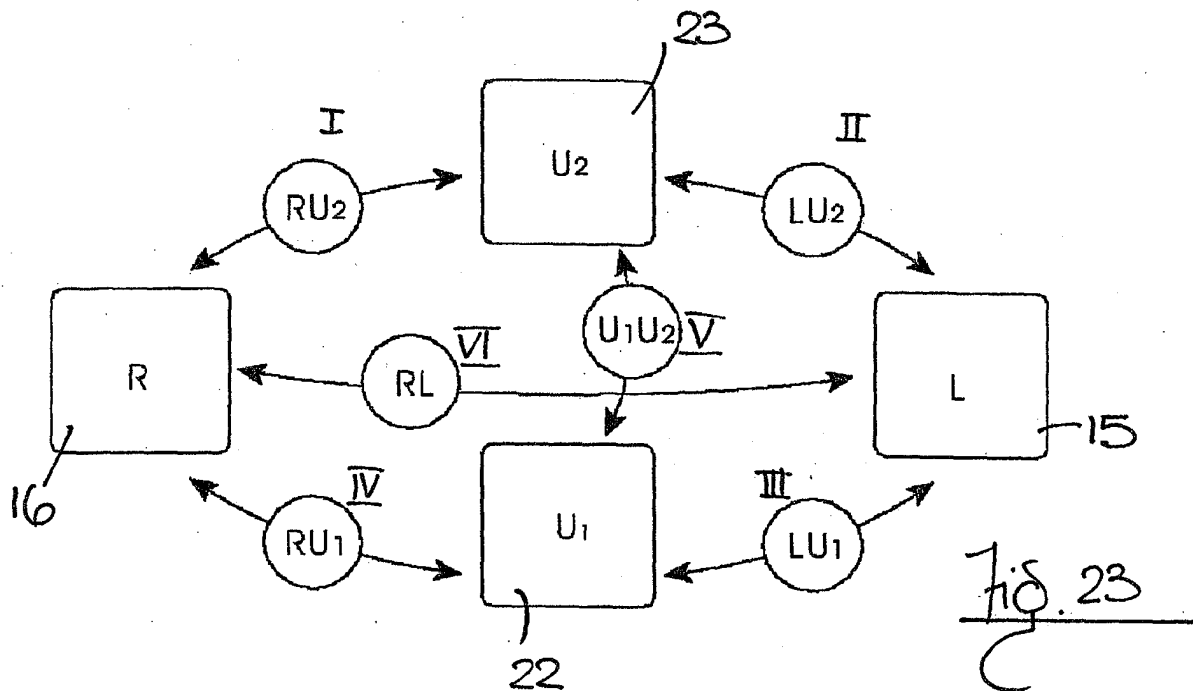


Fig. 22

INFORMAL

10/16



INFORMAL

11/16

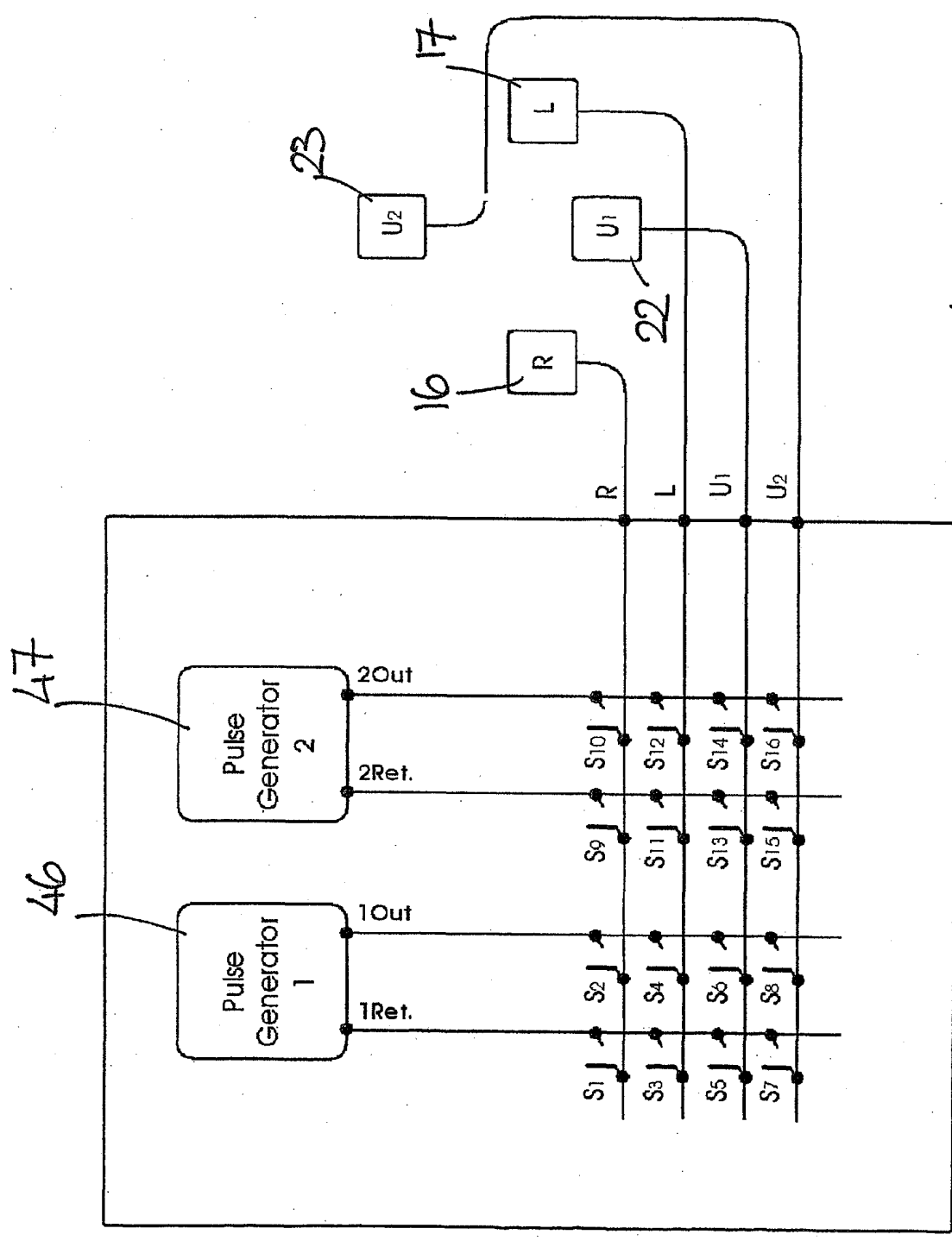


Fig. 25

INFORMAL

12/16

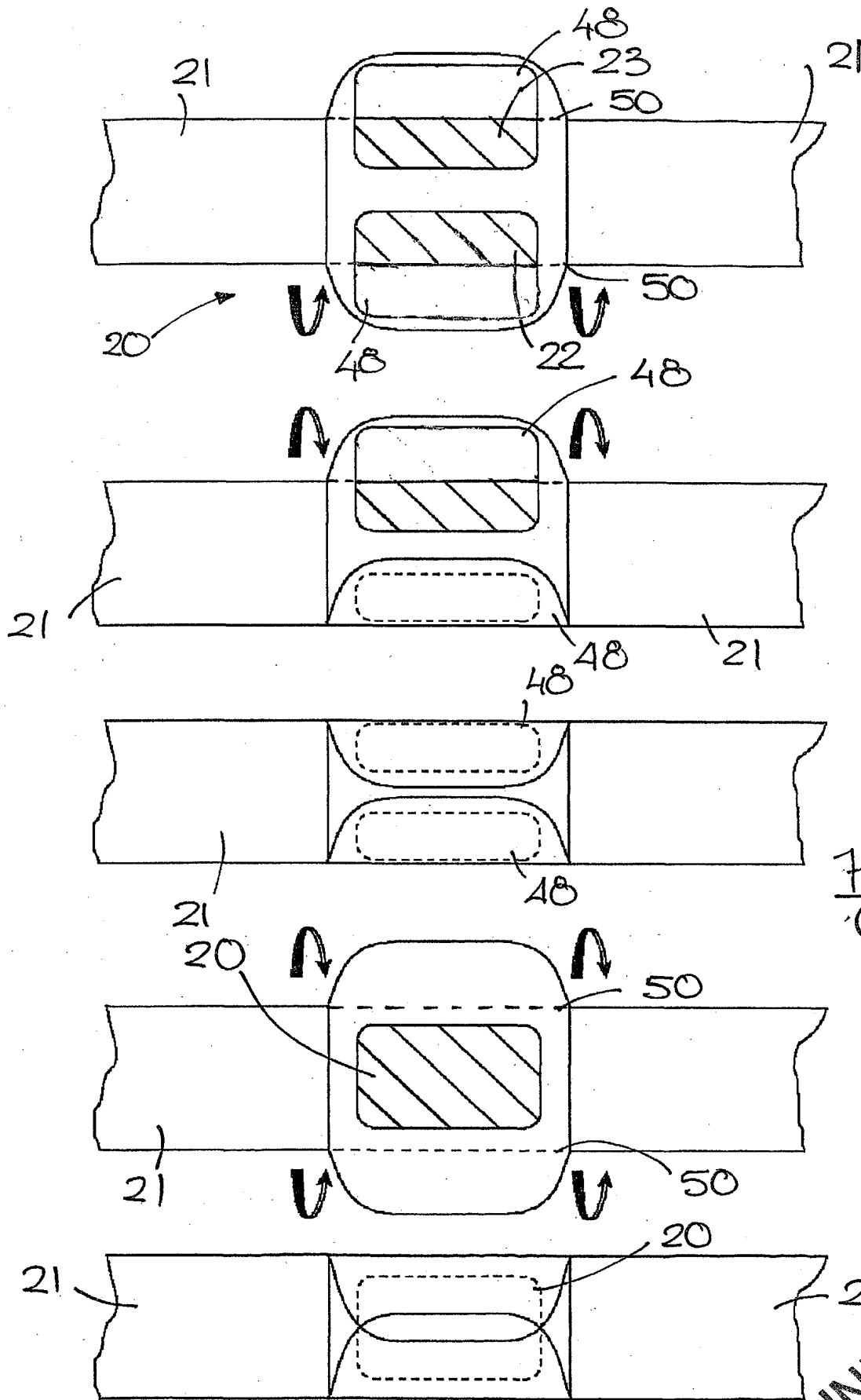
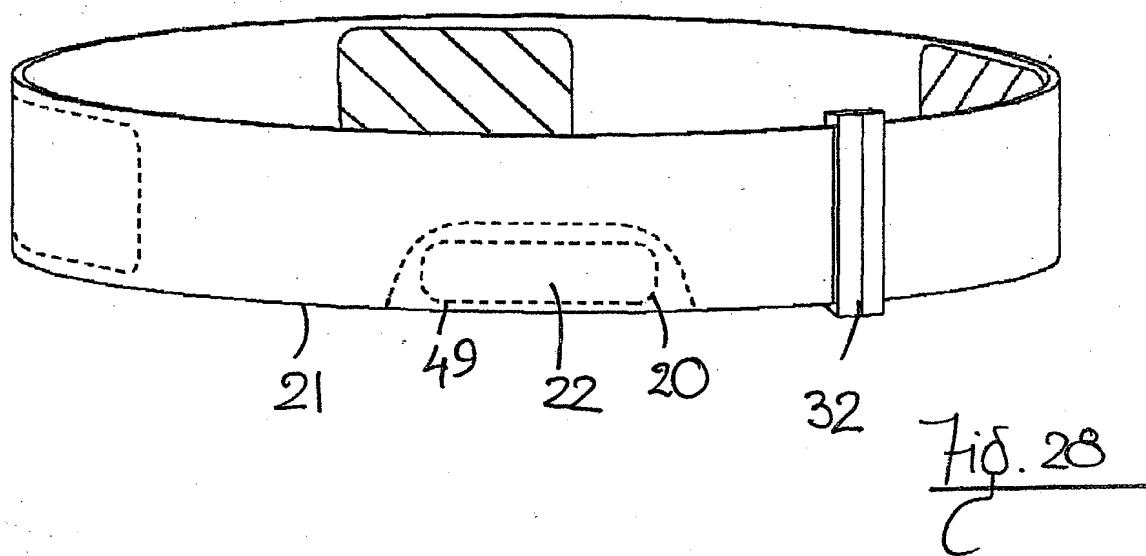
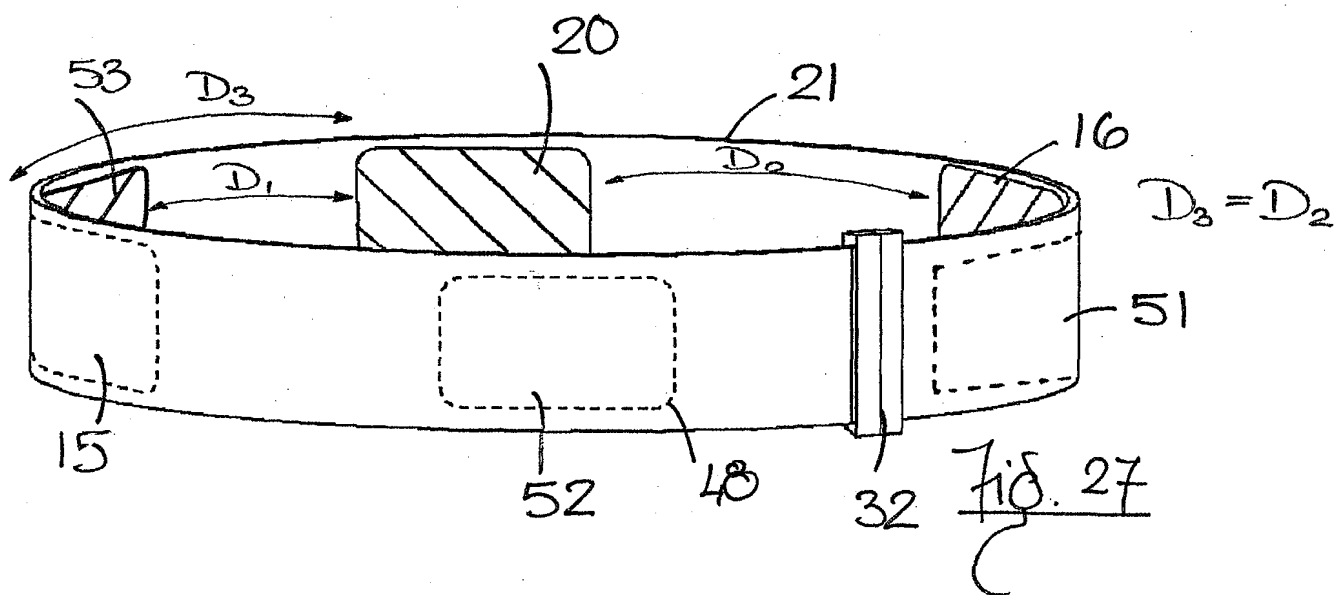
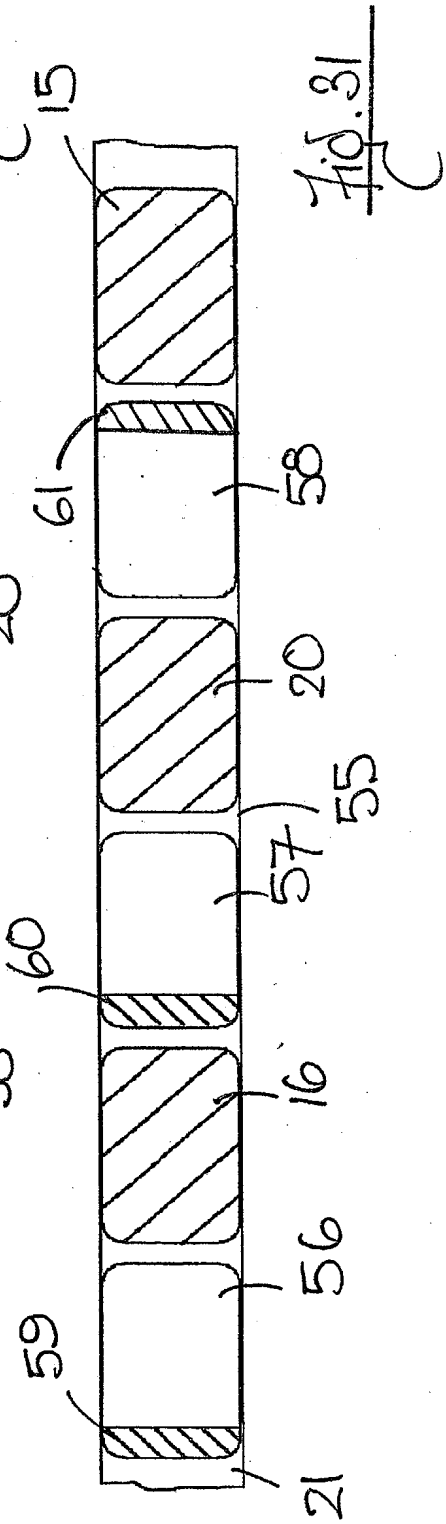
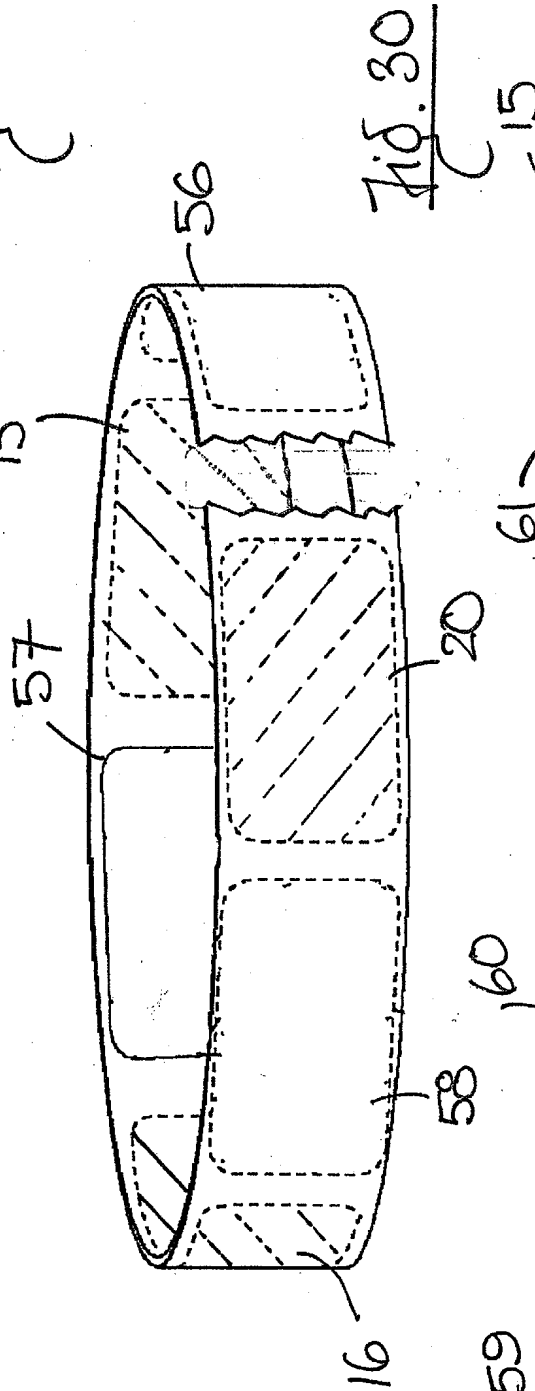
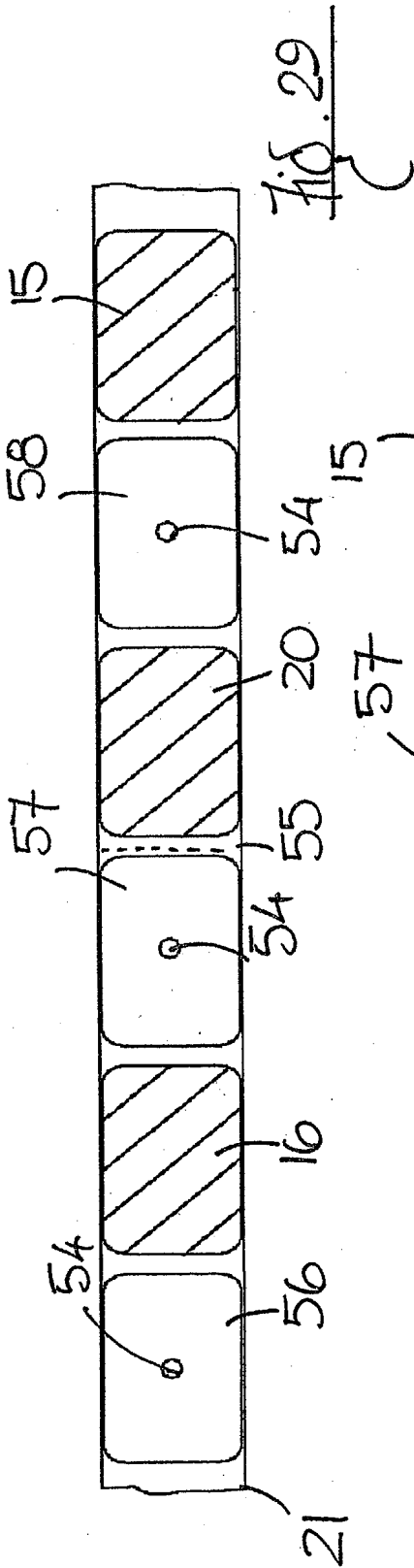


FIG. 26a

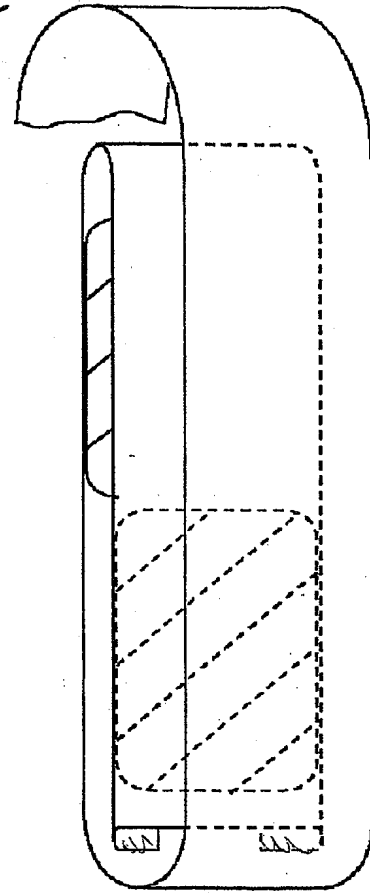
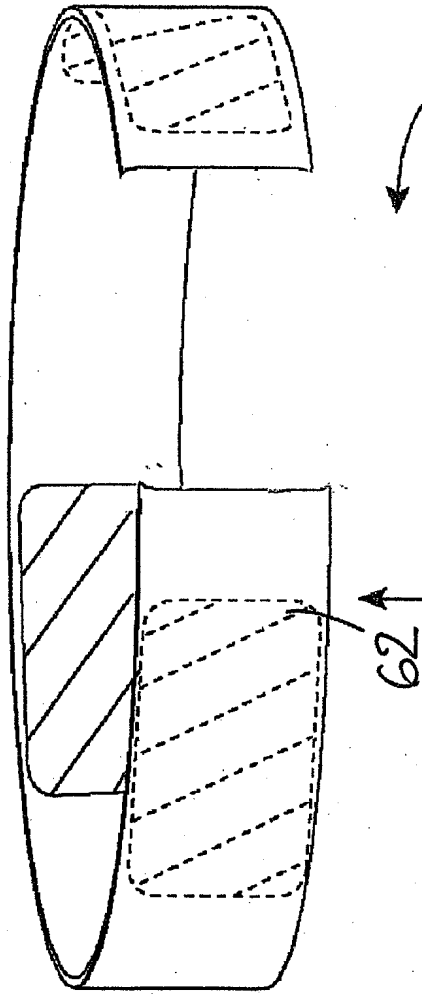
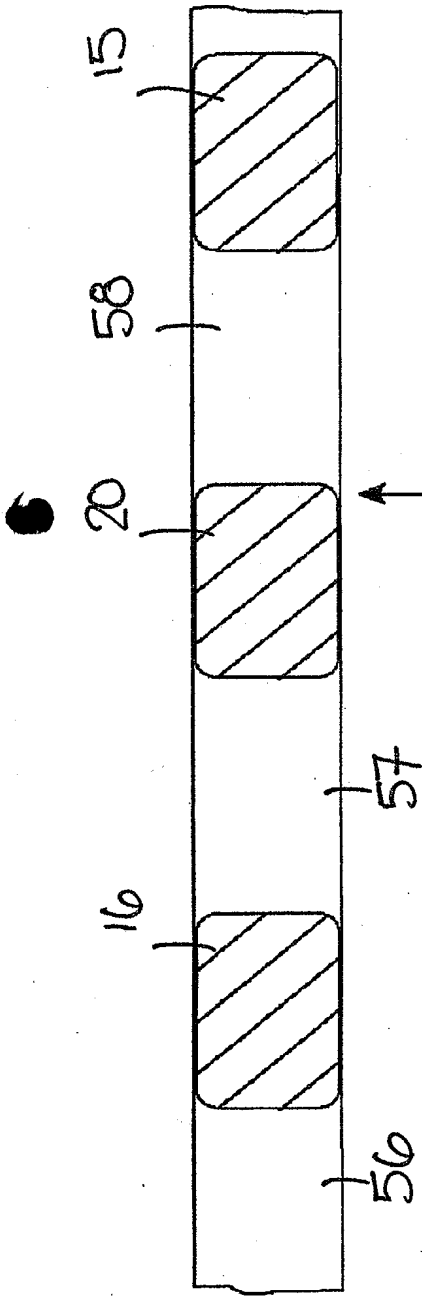
INFORMAL
FIG. 26b



INFORMAL



INFORMAL



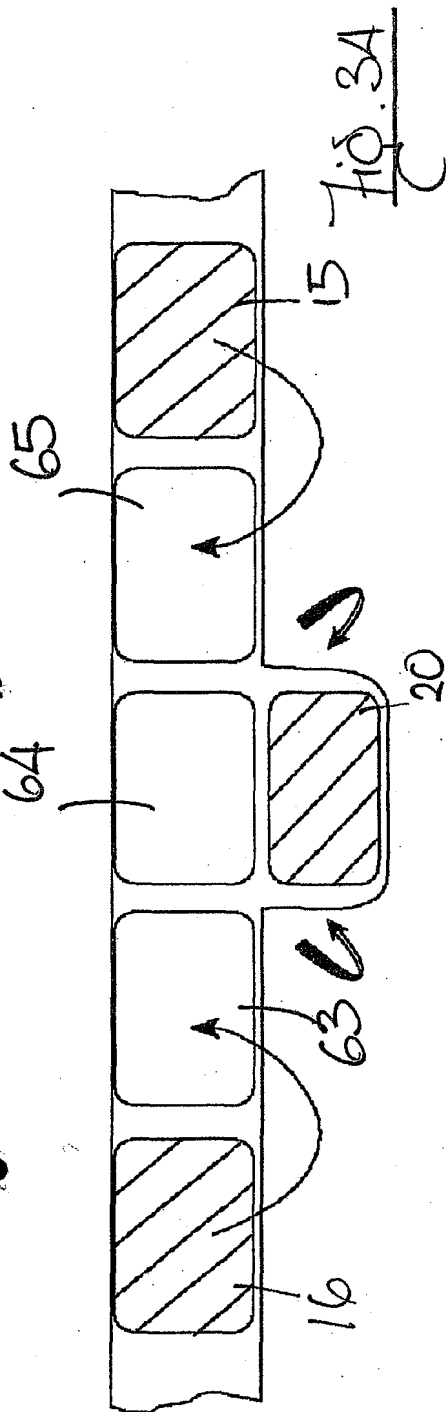


Fig. 34

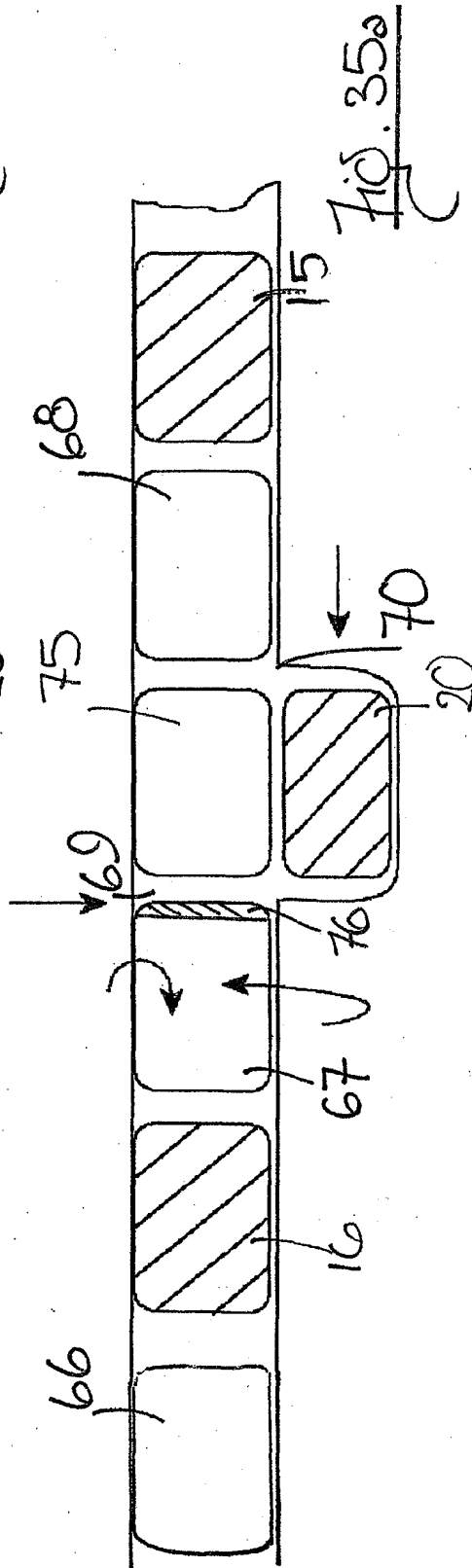


Fig. 35a

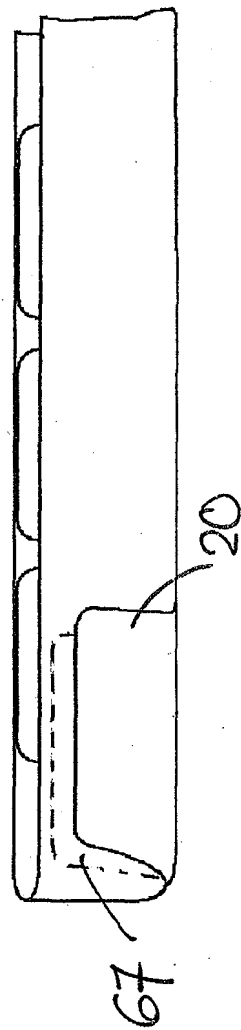


Fig. 36

INFORMAL